

**To:** Bennett, Tate[Bennett.Tate@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Thur 6/22/2017 7:16:11 PM  
**Subject:** Fwd: East Chicago Petition Denial  
[20170512-nrdc-petition-rollout-v2.docx](#)  
[ATT00001.htm](#)  
[Hot Topics 05-12-2017.docx](#)  
[ATT00002.htm](#)  
[EC Petition Response 4-27-17 .docx](#)  
[ATT00003.htm](#)

Hey Tate, is this something you were looking at? I have no clue who Robin is waiting to hear from.

Begin forwarded message:

**From:** "Torma, Tim" <[Torma.Tim@epa.gov](mailto:Torma.Tim@epa.gov)>  
**Date:** June 22, 2017 at 1:29:53 PM EDT  
**To:** "Bolen, Brittany" <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Cc:** "Richardson, RobinH" <[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>  
**Subject:** East Chicago Petition Denial

Brittany,

## Deliberative Process / Ex. 5

I did not have it on the pending items list but will add it.

Have you heard anything about where that stands or who is making the decision on it? Thanks for any insight or advice you can provide.

TT

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**From:** Torma, Tim  
**Sent:** Friday, May 12, 2017 5:53 PM  
**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Cc:** Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>; Flynn, Mike <[Flynn.Mike@epa.gov](mailto:Flynn.Mike@epa.gov)>; Richardson, RobinH <[Richardson.RobinH@epa.gov](mailto:Richardson.RobinH@epa.gov)>; Rees, Sarah <[rees.sarah@epa.gov](mailto:rees.sarah@epa.gov)>; Freire, JP <[Freire.JP@epa.gov](mailto:Freire.JP@epa.gov)>; Schwab, Justin <[schwab.justin@epa.gov](mailto:schwab.justin@epa.gov)>  
**Subject:** 05/12 Hot Topics with revised to-do column and additional items

Brittany,

Attached is the Hot Topics file from today with revisions.

Items added include:

- EPA R5 intention to approve US Army Corps of Engineers to dispose of PCB contaminated sediments in a Confined Disposal Facility (CDF) located in East Chicago, Indiana.

## Deliberative Process / Ex. 5

Please let me know if you need more info on any items or if I got the follow-up wrong. Have a great weekend.

TT

Tim Torma  
Senior Advisor  
U.S. EPA Office of Policy  
202-566-2864

**To:** Schwab, Justin[schwab.justin@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Thur 6/8/2017 11:00:20 PM  
**Subject:** FW: landfills  
**EO12866** Landfills NSPS Stay 2060-AT60 Proposal 20170526 OMB comments (00....docx

**From:** Rees, Sarah  
**Sent:** Thursday, June 8, 2017 6:37 PM  
**To:** McGartland, Al <McGartland.Al@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Corrales, Mark <Corrales.Mark@epa.gov>  
**Subject:** RE: landfills

Hi folks – I’ve attached the comments. Also below is a summary from Jan Gilbreath who is the staff person covering this for ORPM. Al – Elizabeth has been involved from your shop, and I know that Jan has worked hard to ensure NCEE is invited to any OMB meetings – at least the ones we are aware of.

Al 

Deliberative Process / Ex. 5

This update is from 11:30am today; there was apparently another call with OMB and DOJ later in the day where DOJ reiterated the 

Deliberative Process / Ex. 5

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Deliberative Process / Ex. 5

The issues at play:

Deliberative Process / Ex. 5

**To:** Rees, Sarah[rees.sarah@epa.gov]; Nickerson, William[Nickerson.William@epa.gov]  
**Cc:** Dravis, Samantha[dravis.samantha@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Tue 6/27/2017 2:57:21 PM  
**Subject:** FW: Questions for the record - house hearing  
HAC QFRs for policy team and others.docx

Hi Sarah and Bill –

We've been asked to work on the Reg Reform responses to the QFRs attached. I can't readily locate the QFR responses the three of us had worked on a week or so ago, but could you please refer to those responses and prepare draft responses to the attached reg reform questions? Our final responses are due Friday by noon. That said, could you please provide us draft responses by COB tomorrow?

Thanks,  
Brittany

**From:** Burton, Tamika  
**Sent:** Fri 7/28/2017 5:48:05 PM  
**Subject:** Updated: Agency Weekly Report 07282017  
[Weekly report 07282017.docx](#)

Hello,  
If you are having difficulty viewing the file, please see attached.

Best Regards,  
*Tamika Burton*  
*Staff Assistant*  
*Office of the Deputy Administrator*  
*MC 1104A Room 3412 WJC North*  
*(202) 564-4771 (d)*  

Personal Phone / Ex. 6 (c)

  
[burton.tamika@epa.gov](mailto:burton.tamika@epa.gov)

---

**From:** Burton, Tamika  
**Sent:** Friday, July 28, 2017 1:42 PM  
**Subject:** Agency Weekly Report 07282017

Good Afternoon,  
Please see the attached weekly report.

Best regards,

*Tamika Burton*  
*Staff Assistant*  
*Office of the Deputy Administrator*  
*MC 1104A Room 3412 WJC North*  
*(202) 564-4771 (d)*  

Personal Phone / Ex. 6 (c)

  
[burton.tamika@epa.gov](mailto:burton.tamika@epa.gov)



**To:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]; Greenwalt, Sarah[greenwalt.sarah@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Beck, Nancy[Beck.Nancy@epa.gov]; Yamada, Richard (Yujiro)[yamada.richard@epa.gov]; Brown, Byron[brown.byron@epa.gov]; Kelly, Albert[kelly.albert@epa.gov]; Traylor, Patrick[traylor.patrick@epa.gov]; Bowman, Liz[Bowman.Liz@epa.gov]; Ringel, Aaron[ringel.aaron@epa.gov]; Palich, Christian[palich.christian@epa.gov]  
**Cc:** Lyons, Troy[lyons.troy@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]  
**From:** Greaves, Holly  
**Sent:** Tue 6/27/2017 12:04:45 PM  
**Subject:** Questions for the record - house hearing  
HAC QFRs for policy team and others.docx

Good morning! We have received questions for the records from our house hearing. The turnaround is very tight, unfortunately, and we need to get responses pulled together **by noon on Friday**.

Given the nature of certain questions, I've identified those in yellow for which I think the political team is more suited to answer (see attached). The OCFO and other offices will work with OCIR on the remaining responses. Troy and I will review all responses before they are provided to OMB.

I will send more specific lists after today, but generally speaking I am asking that you work to respond to those questions suited to your area of expertise:

- Samantha/Brittany – regulatory reform questions
- Mandy – Air questions
- Sarah – Water questions
- Nancy – Chemicals
- Patrick Traylor – Enforcement
- Byron Brown/Kel – Land/Superfund
- Liz – questions about travel or other personal matters

Feel free to reach out to me or your office if your response requires specific numbers or other details you don't quickly have at your disposal.

Thanks,  
Holly

**From:** Burton, Tamika  
**Sent:** Fri 8/4/2017 5:50:33 PM  
**Subject:** Weekly Report 08042017  
[Weekly Report 08042017.docx](#)

Good Afternoon,

Please see attached the weekly report for this week.

Best regards,

*Tamika Burton*

*Staff Assistant*

*Office of the Deputy Administrator*

*MC 1104A Room 3412 WJC North*

*(202) 564-4771 (d)*

*Personal Phone / Ex. 6 : (c)*

*burton.tamika@epa.gov*



**From:** Burton, Tamika  
**Sent:** Fri 5/12/2017 7:06:13 PM  
**Subject:** Weekly Report - 05/12/2017  
[5122017.docx](#)

Goof Afternoon,

Please see the attached report for this week's report compilation.

Best regards,

*Tamika Burton*

*Staff Assistant*

*Office of the Deputy Administrator*

*MC 1104A Room 3412 WJC North*

*(202) 564-4771 (d)*

**Personal Phone / Ex. 6**

*burton.tamika@epa.gov*





**From:** Burton, Tamika  
**Sent:** Fri 7/28/2017 5:48:05 PM  
**Subject:** Updated: Agency Weekly Report 07282017  
[Weekly report 07282017.docx](#)

Hello,  
If you are having difficulty viewing the file, please see attached.  
Best Regards,  
*Tamika Burton*  
*Staff Assistant*  
*Office of the Deputy Administrator*  
*MC 1104A Room 3412 WJC North*  
*(202) 564-4771 (d)*  

Personal Phone / Ex. 6

(c)

  
[burton.tamika@epa.gov](mailto:burton.tamika@epa.gov)

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**From:** Burton, Tamika  
**Sent:** Friday, July 28, 2017 1:42 PM  
**Subject:** Agency Weekly Report 07282017  
Good Afternoon,  
Please see the attached weekly report.  
Best regards,  
*Tamika Burton*  
*Staff Assistant*  
*Office of the Deputy Administrator*  
*MC 1104A Room 3412 WJC North*  
*(202) 564-4771 (d)*  

Personal Phone / Ex. 6

(c)

  
[burton.tamika@epa.gov](mailto:burton.tamika@epa.gov)



**To:** Campbell, Jennie[Campbell.Jennie@epa.gov]  
**From:** Kenny, Shannon  
**Sent:** Thur 6/8/2017 7:09:56 PM  
[OP 2017 reorg.docx](#)

Here is justification I shared with Brittany:

Shannon Kenny  
Principal Deputy Associate Administrator  
U.S. EPA Office of Policy

**Personal Phone / Ex. 6**

**To:** Dravis, Samantha[dravis.samantha@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]  
**Cc:** Lopez, George[lopez.george@epa.gov]  
**From:** Lovell, William  
**Sent:** Mon 6/26/2017 11:33:29 PM  
**Subject:** 6/28 Presentation Prep Materials  
[C85 CCI June Attendees.pdf](#)  
[C85 CCI June Meetings Agenda.pdf](#)  
[Class of '85.v2.docx](#)  
[Reg Reform Comment.pdf](#)  
[Reg Reform Stakeholder Meetings talking points June 2017.docx](#)

Please find attached the materials for tomorrow's meeting to **prep for Samantha's 6/28 Regulatory Reform Presentation to U.S. Electric Generating Companies.**

I placed these materials on top of your schedules.

**Will Lovell**

Policy Assistant, Office of Policy  
U.S. Environmental Protection Agency  
(202) 564-5713  
[Lovell.William@epa.gov](mailto:Lovell.William@epa.gov)

# Class of '85/Cross-Cutting Issues Group Meetings

28 June 2017

| NAME                  | COMPANY                         |
|-----------------------|---------------------------------|
| AMOS, Jonathan        | Xcel Energy                     |
| BAHTIC, Nedin         | Lakeland Electric               |
| BARRETT, Justin       | AES                             |
| BARTON, Elvy          | Salt River Project              |
| BLOUNT, Will          | PowerSouth Electric Cooperative |
| BURROWS, Byron        | Tampa Electric                  |
| CASH, Rebecca         | LG&E and KU                     |
| CASHIN, Mike          | Minnesota Power                 |
| COLLIER, Angelique    | AES                             |
| EATON, Kristin        | Florida Power &Light            |
| FLOYD, Susan Margaret | Entergy                         |
| FROSCH, Deborah       | Alliant                         |
| GANNON, Maureen       | Public Service New Mexico       |
| GLESS, Jodie          | Florida Power &Light            |
| GRESS, Benjamin       | Great River Energy              |
| HAMPP, John           | Florida Power &Light            |
| HARDEN, Tim           | Alliant                         |
| HILLESHEIM, David     | Xcel Energy                     |
| HOCH, Joe             | Alliant                         |
| HORN, Claudette       | Public Service New Mexico       |
| HUFF, Don             | Dairyland Power Cooperative     |
| JOHNSON, Rick         | Entergy                         |
| KAUFER, Iian          | Florida Power &Light            |
| KNOWLES, Berdell      | JEA                             |
| LEAF, Patti           | Xcel Energy                     |

# Class of '85/Cross-Cutting Issues Group Meetings

28 June 2017

| NAME                    | COMPANY                          |
|-------------------------|----------------------------------|
| LOIACANO, Jennifer      | Arkansas Electric Cooperatives   |
| MARTIN, Nick            | Xcel Energy                      |
| McQUEEN, Kelly          | Entergy                          |
| McQUOWN, Brian          | Oklahoma Gas &Electric           |
| MILLER, Cris            | Basin Electric Power Cooperative |
| MONTALVO, Kara          | Salt River Project               |
| NELSON, Deb             | Great River Energy               |
| PAULSON, John           | Minnesota Power                  |
| PLUTA, Michele          | Alliant                          |
| REIMANN, Jon            | AES                              |
| REVLETT, Gary           | LG&E and KU                      |
| RIEHL, Carissa          | Great River Energy               |
| ROTH, Mary Jo           | Great River Energy               |
| ROSVOLD, Rick           | Xcel Energy                      |
| SEHA, Ann               | Xcel Energy                      |
| SHAMORY, Craig          | Talen Energy                     |
| SHEA, Eric              | Florida Power &Light             |
| SMITH, Jennifer Thulien | Xcel Energy                      |
| SOLE, Michael           | NextEra Energy                   |
| STEPHENS, Keith         | PowerSouth Electric Cooperative  |
| TOKARCZYK, Crystal      | Minnesota Power                  |
| TREANOR, Elysia         | Portland General Electric        |
| TURNER, Usha            | Oklahoma Gas & Electric          |
| TUTTLE, Tomey           | Florida Power &Light             |
| WEGLARZ, Melissa        | Minnesota Power                  |
| WILKUS, Dan             | Westar                           |

# **Class of '85/Cross-Cutting Issues Group Meetings**

28 June 2017

## **BAKER BOTTS:**

**Berge, Megan**

**Bumpers, Bil**

**Jezouit, Debra**

**Mallick, Allison**

# CLASS OF '85 REGULATORY RESPONSE GROUP MEETING AGENDA

Great River Energy Office  
12300 Elm Creek Blvd.,  
Maple Grove, MN 55369

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**June 27, 2017 (9:15 a.m. – 3:15 p.m. Central)**

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Coffee and pastries (9:00 a.m. – 9:15 a.m.)

**I. Introduction & Update on Issues (9:15 a.m. – 10:00 a.m.)**

- A. EPA Analysis of Air Regulation Impacts on Jobs
- B. Challenge to the Congressional Review Act
- C. “Sue and Settle” Developments
- D. Treatment of Malfunctions in MACT Standards

**II. Opacity Litigation (10:00 a.m. – 10:30 a.m.)**

- A. Citizen Suits: Alleged Opacity Violations
- B. Opacity Monitoring Issues

Break (10:30 a.m. – 10:45 a.m.)

**III. Regulatory Reform Update (10:45 a.m. – 11:30 a.m.)**

- A. OMB Guidance Documents
- B. Two-for-One Executive Order
- C. Summary of Comments on EPA Regulatory Reform
- D. Status of EPA Regulatory Reform Task Force
- E. Status of EPA’s Reconsideration of Rules

**IV. Roundtable Discussion: Class of ‘85 Regulatory Reform Strategy (11:30 a.m. – 12:15 p.m.)**

- A. RICE Issues
- B. Monitoring Requirements
- C. Modeling Issues
- D. Other Issues

Lunch Break (12:15 p.m. – 1:15 p.m.)

**V. Guest Speaker Presentation on the New State-Federal Relationship (1:15 p.m. – 2:15 p.m.)**

- A. David Thornton, Assistant Commissioner for Air Policy, Minnesota Pollution Control Agency

Break (2:15 p.m. – 2:30 p.m.)

**VI. Regional Haze (2:30 p.m. – 3:15 p.m.)**

- A. Regional Haze FIP Challenges
- B. Challenges to Regional Haze Revision Rule
- C. CSAPR > BART
- D. Preparing for the Second Planning Period

**June 28, 2017 (9:00 a.m. – 1:15 p.m. Central)**

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Coffee and pastries (8:45 a.m. – 9:00 a.m.)

**I. Climate Change Issues (9:00 a.m. – 9:45 a.m.)**

- A. Review and Replacement of the Clean Power Plan
- B. Public Trust Climate Litigation
- C. State Climate Initiatives

**II. NSR/Enforcement Issues (9:45 a.m. – 10:30 a.m.)**

- A. Status of Ongoing Enforcement Cases and Citizen Suits
- B. Lessons Learned From *Ameren*

Break (10:30 a.m. – 10:45 a.m.)

**III. NAAQS and Interstate Transport Issues (10:45 a.m. – 11:15 a.m.)**

- A. Section 126 Petitions
- B. Status of 2015 Ozone NAAQS
- C. Upcoming NAAQS Reviews

**IV. Class Action Tort Litigation (11:15 a.m. – 11:45 a.m.)**

- A. Trends in Class Action and Toxic Tort Litigation
- B. Best Practices for Avoidance and Defense

Break (11:45 a.m. – 12:15 p.m.)

**V. Working Lunch: Discussion With EPA Office of Policy About Regulatory Reform (12:15 p.m. – 1:15 p.m.)**

*Joint with Cross-Cutting Issues Group*

- A. Samantha Dravis, Associate Administrator, EPA Office of Policy
- B. Sarah Rees, Director, Office of Regulatory Policy and Management, EPA Office of Policy



## CROSS-CUTTING ISSUES GROUP MEETING AGENDA

Great River Energy Office  
12300 Elm Creek Blvd.,  
Maple Grove, MN 55369

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**June 28, 2017 (12:15 p.m. - 4:30 p.m. Central)**

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**I. Working Lunch: Discussion With EPA Office of Policy About Regulatory Reform (12:15 p.m. – 1:15 p.m.)**

*Joint with Class of '85 Regulatory Response Group*

- A. Samantha Dravis, Associate Administrator, EPA Office of Policy
- B. Sarah Rees, Director, Office of Regulatory Policy and Management, EPA Office of Policy

Break (1:15 p.m. – 2:00 p.m.)

**II. Update on Issues (2:00 p.m. – 2:15 p.m.)**

- A. PCB Rulemaking
- B. Litigation Update
- C. Pipeline Update

**III. Status of Agency Regulatory Reform Efforts (2:15 p.m. – 2:45 p.m.)**

- A. Summary of Comments on EPA Regulatory Reform
- B. Status of EPA's Reconsideration of Rules
- C. Status of Department of Interior Regulatory Reform

**IV. Water Reform: Developments and Strategy (2:45 p.m. – 3:30 p.m.)**

- A. Effluent Limitation Guidelines
- B. WOTUS White Paper and Strategy for Agency Outreach
- C. Client Roundtable: 316(b) / Cooling Water Intake Rule; Nutrient Reduction

**V. Wildlife Reform: Strategy Discussion (3:30 p.m. – 4:00 p.m.)**

- A. Memorandum 37041 on MBTA Liability
- B. 2016 Critical Habitat Regulations and Policy
- C. FWS Mitigation Policies

**VI. Coal Ash Developments (4:00 p.m. – 4:30 p.m.)**

- A. EPA Guidance on Coal Ash Permitting Programs
- B. CWA Liability for Discharges to Groundwater

## Overview of Comments of the Class of '85 Regulatory Response Group on Regulatory Reform

The Class of '85 Regulatory Response Group is a voluntary ad hoc coalition of approximately 30 electric generation companies from around the country that has been actively involved in the development of Clean Air Act rules and guidance affecting the electric generating industry for over 25 years.

The Class of '85 own and operate electric generating units (EGUs) subject to the CAA in approximately 35 states throughout the country.

### Summary of Key Comments

#### A. EPA Should Streamline Recordkeeping and Reporting Requirements to Eliminate Duplicative Obligations

##### GHG Emissions Reporting

- **Summary of Issue:** There is an overlap in emissions reporting requirements under two part of the Code of Federal Regulations (Part 75 and Part 98). By streamlining the reporting process, the electric industry would reduce the reporting resources needed.
- EPA established Part 75 in 1993 to establish continuous emission monitoring and reporting requirements in support of EPA's Acid Rain Program. The program regulates EGUs that burn fossil fuels such as coal, oil and natural gas and have a generator capacity of greater than 25 megawatts. For these units, Part 75 requires continuous monitoring and reporting of sulfur dioxide (SO<sub>2</sub>) mass emissions, CO<sub>2</sub> mass emissions, nitrogen oxides (NO<sub>x</sub>) emission rate, and heat input.
- Part 98, referred to as the Greenhouse Gas Reporting Program (GHGRP), is a mandatory rule for reporting greenhouse gases from sources that emit 25,000 metric tons or more of CO<sub>2</sub>e each year. Part 98.32 requires reporting of CO<sub>2</sub>, methane (CH<sub>4</sub>), and nitrous oxide (N<sub>2</sub>O) mass emissions from each stationary fuel combustion unit on an annual basis.
- Reporting under Parts 75 and 98 could be consolidated to reduce the reporting obligations for the electric sector by automatically populating specific CO<sub>2</sub> emissions and heat input information entered in an EPA system under Acid Rain Program into the GHG reporting system.
- **EPA Response:** The agency does not appear to have publicly announced an effort to address this issue, but OAR, in its 5/15/17 memorandum responding to the Regulatory Reform Task Force, indicated a willingness to review this issue.

##### Maximum Achievable Control Technology (MACT) Reports

- **Summary of Issue:** The Class of '85 suggests the elimination of duplicative reporting requirements in general, and for the Boiler MACT in particular.
- They offer as an example that the Boiler MACT regulations in Part 63 require semi-annual compliance reports which are to include information on any deviations from an emission limit or operating limit. (40 CFR §63.7550(d)). The Title V regulations in Part 70 (state operating permits) contains a similar semi-annual compliance reporting requirement for deviations from permitting requirements. (40 CFR §70.6(3)(iii)).
- The Class of '85 suggests eliminating the requirement in Part 63 to the extent it duplicates requirements in Part 70.

- **EPA Response:** Your identification of a specific duplicative reporting requirement is very helpful and your suggested remedy appears to be quite sensible. To the extent that there are duplicative reporting requirements, it would make sense to roll them into the Title V permitting program.

#### **Title V Permitting Program**

- **Summary of Issue:** Title V of the CAA requires major sources and some non-major sources to obtain and operate in compliance with an operating permit that contains all applicable CAA requirements for the source.
- The Class of '85's comment on the Title V program pertains to the overlap between the reporting requirements in the National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Industrial, Commercial, and Institutional and Process Heaters ("Boiler MACT") and Title V regulations. They urge EPA to streamline these regulations to reduce the regulatory burden on industry and the administrative burden on EPA.
- **EPA Response:** Your identification of duplicative reporting requirements is helpful. See also the discussion under Boiler MACT, above.

#### **Part 64 Compliance Assurance Monitoring (CAM)**

- **Summary of Issue:** The Compliance Assurance Monitoring (CAM) Rule was promulgated in 1997. CAM establishes procedures intended to provide a reasonable assurance of compliance with applicable CAA requirements for large emission units that rely on pollution control device equipment to achieve compliance.
- CAM requires monitoring be conducted to determine that control measures, once installed or otherwise employed, are properly operated and maintained so that they continue to achieve a level of control that complies with applicable requirements.
- The Class of '85 suggests that outdated Part 64 CAM provisions be eliminated. They offer as an example that electrostatic precipitator ("ESP") power monitoring under CAM has been rendered unnecessary by newer technologies and more recent regulations and should be eliminated. They provide a citation to 40 CFR §64.3, but there appears to be no reference to ESPs in that section.
- **EPA Response:** EPA agrees that unnecessary and outdated regulations should be removed or revised. In the ESP example you gave, more detail would be helpful. Are ESPs explicitly or implicitly controlled by provisions in 40 CFR §64.3? What specific regulatory text changes would you suggest?

#### **B. EPA Should Eliminate Monitoring and Testing Requirements That Provide No Environmental Benefits.**

#### **CEMS Certifications on Bypass Stacks**

- **Summary of Issue:** The Class of '85 requested that EPA reduce the MATS requirement for CEMS certification on bypass stacks in cases where bypass stacks are rarely used.
- **EPA response:** My understanding is that the 2014 MATS reconsideration made an adjustment to how bypass stacks were addressed in the context of monitoring and testing requirements. Specifically, the final reconsideration provided options if it is not feasible to certify and QA the data from a CEMS. Units can route the exhaust from the bypass through the main stack (and

monitor bypass emissions, if any, that way) OR just use the CEMS on the main stack and count hours that the bypass stack is in use as hours of deviation from the monitoring requirements.

- Did these revisions address your concerns or do you have additional suggestions for CEMS certification on bypass stacks?

### **Tuning Requirements for New/Modified Units**

- **Summary of Issue:** The Class of '85 suggested that EPA should exempt new and modified units with best available control technology ("BACT") limits from the initial MATS nitrogen oxides ("NOx") and carbon monoxide ("CO") tuning requirements.
- **EPA Response:** The tuning requirements are structured as work practice standards to offer flexibility and they help ensure that the burners are in good working order, the controls, as installed, are working properly and the system has been correctly tuned. These requirements also need to be met by when new units are installed.
- If new units were exempt from the requirements, how could EPA ensure that the burners are in good working order?

### **C. EPA Should Revise Maintenance Requirements That Provide No Environmental Benefits.**

#### **Boiler Tune-Ups**

- **Summary of Issue:** The Boiler MACT regulations at 40 CFR §63.7515 require an annual tune-up (i.e., boiler adjustment) be conducted "no more than 13 months after the previous tune-up."
- The Class of '85 notes that tracking a compliance deadline based on a calendar year is significantly more manageable than tracking a compliance deadline that does not occur on the same date each year, and, therefore suggests tune-ups be required once every calendar year.
- **EPA Response:** EPA is very interested in providing industry sensible, needed flexibility. Although the current regulation allows 13 months between tune-ups, it doesn't require that facilities wait that full time. A facility can choose to conduct the tune-up at the same time every year. Does this flexibility address your concern?

#### **RICE MACT and NSPS**

- **Summary of Issues:** Stationary engines, also called reciprocating internal combustion engines (RICE), are commonly used at power and manufacturing plants for emergency and non-emergency operations to generate electricity and to power pumps and compressors.
- Requirements vary depending on engine type (gasoline or diesel), engine size (by horsepower), number of hours run per year, and designation as "emergency" or "non-emergency" engines.
- Class of '85 provides several recommendations to reduce tracking, maintenance, and reporting burden, including reducing requirements on infrequently run engines and small emergency engines.
- They also want EPA to increase the number of hours that large engines can run prior to triggering certain requirements, to allow engine operators to develop their own operation and maintenance plans for emergency engines instead of following manufacturer's instructions, and to extend the deadline for performing oil changes.

- In addition, they want EPA to revise the definition of an “emergency situation” to include planned situations when power is not available so that they can use on-site non-emergency engines to provide replacement power rather than renting off-site engines.
- **EPA Response:** EPA appreciates your comments on the RICE MACT and NSPS. As we evaluate the requirements for these engines, we would like to discuss these comments with you in more detail.

#### **D. Additional Recommendations to Reduce Regulatory Burdens**

##### **Low-Emitting EGUs Under MATS**

- **Summary of Issue:** The Class of ‘85 recommends that EPA amend the MATS provisions addressing the demonstration of low-emitting EGU (“LEE”) status to permit use of actual unit operating data, rather than potential maximum operating data.
- The low emitting EGU (or LEE) approach for existing sources represents another of the emissions quantification flexibilities provided by MATS. In exchange for demonstrating and maintaining emissions much lower than those required by the rule, EGU owners or operators are able to avoid installation and operation of sophisticated measurement instruments. Demonstrating LEE status allows units to extend the duration of time between ongoing testing to demonstrate compliance as well as to re-verify LEE program eligibility.
- **EPA Response:** As of 2016, 11% of MATS EGUs have LEE status. EPA understands that you would like more units to achieve LEE status and will consider your suggestions for how to change the provisions to allow more units to be eligible.

##### **MATS Residual Risk Review**

- **Summary of Issue:** The Group strongly recommends that EPA complete the residual risk and technology review for coal-fired power plants covered by the MATS. EPA is statutorily required to assess the risk remaining after the implementation of a specific NESHAP within 8 years of the final NESHAP. For MATS, EPA will need to complete this review by 2020.
- **EPA Response:** At this time, EPA is working to complete residual risk and technology reviews for multiple source categories. That said, we can always adjust how we prioritize these reviews while still meeting statutory deadlines.

##### **Acid Rain Program**

- **Summary of Issue:** The Acid Rain Program requires electric power plants to reduce emissions of sulfur dioxide (“SO<sub>2</sub>”) and nitrogen oxides (“NO<sub>x</sub>”), the primary precursors of acid rain. The program also establishes monitoring requirements for SO<sub>2</sub>, NO<sub>x</sub> and CO<sub>2</sub> emissions, volumetric flow and opacity data from affected units.
- According to the Class of ‘85, ultrasonic meters are the most accurate type of instrument for measuring volumetric flow rates of natural gas, but are subject to more complicated regulatory requirements because they are not explicitly approved under the acid rain monitoring regulations in Appendix D or Appendix E of 40 CFR Part 75. They urge EPA to update the regulations to explicitly approve the use of these monitors.
- **EPA Response:** EPA appreciates your comments and would like to discuss the advantages of using the ultrasonic meters over other monitors. Are the ultrasonic monitors cheaper than other monitors approved for use in the Acid Rain Program?

### **“Once In, Always In” Policy**

- **Summary of Issue:** In May 1995, EPA issued implementing guidance for a number of provisions of its nascent MACT program under section 112 of the CAA (which addresses hazardous air pollutants). The guidance stated that once a source becomes subject to a MACT standard it must always remain subject to that standard, even if in the future it reduces its emissions of hazardous air pollutants below the major source thresholds.
- Over the years, EPA has considered making changes to this policy, publishing (but never finalizing) two separate proposals to alter the policy (in May 15, 2003 and January 3, 2007).
- The Class of ‘85 urges EPA to withdraw the 1995 guidance.
- **EPA Response:** We have heard similar comments from multiple sources. The agency does not appear to have publicly announced an effort to address this issue, but OAR, in its 5/15/17 memorandum responding to the Regulatory Reform Task Force, indicated a potential willingness to reconsider the policy. If EPA, withdraws the 1995 guidance, would you like EPA to replace the guidance with a regulation?

### **Clean Power Plan (CPP), New Source Performance Standards for Greenhouse Gas Emissions from New, Modified, and Reconstructed Power Plants (GHG NSPS for Power Plants), and Related Actions**

- Per direction from the President and Administrator Pruitt, EPA has initiated a Review of the CPP and the GHG NSPS for Power Plants, and has withdrawn related regulatory proposals concerning federal plan requirements and model rules for greenhouse gas emissions from power plants.
- *Note: The Class of ‘85 did not comment on this topic.*

**COMMENTS OF THE CLASS OF '85 REGULATORY RESPONSE GROUP**  
**ON THE**  
**REQUEST FOR COMMENTS ON THE “EVALUATION OF EXISTING**  
**REGULATIONS”**

**EPA Docket No. EPA–HQ–OA–2017–0190**

**I. INTRODUCTION**

On April 13, 2017, the U.S. Environmental Protection Agency (“EPA” or “Agency”) published in the *Federal Register*, at 82 Fed. Reg. 17,793, a notice entitled “Evaluation of Existing Regulations” (“Notice”), requesting public comment on regulatory reform issues. The Notice was published in response to Executive Order 13777 (“EO”), entitled “Enforcing the Regulatory Reform Agenda,” which directs federal agencies to establish Regulatory Reform Task Forces (“Task Forces”) to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification, with the goal of alleviating “unnecessary regulatory burdens.”<sup>1</sup> The EO directs the Task Forces to seek input from entities significantly affected by federal regulations in their efforts to identify regulations for reform. EPA’s Notice specifically requests comments on EPA regulations “that may be appropriate for repeal, replacement, or modification.”<sup>2</sup>

The Class of ’85 Regulatory Response Group (“Class of ’85” or “Group”) respectfully submits these comments in response to the Notice.<sup>3</sup> The Class of ’85 is a voluntary ad hoc coalition of approximately 30 electric generating companies from around the country that has been actively involved in the development of Clean Air Act (“CAA”) rules and guidance affecting the electric generating industry for over 25 years. Members of the Class of ’85 own and operate electric generating units (“EGUs”) subject to the CAA in approximately 35 states throughout the country, and will be directly affected by any CAA-related regulations pertaining to the electric generating industry that are repealed, replaced, or modified by EPA.

The Class of ’85 encourages EPA to make targeted edits to certain regulatory requirements that are redundant or unnecessary.<sup>4</sup> The changes proposed in these comments would significantly reduce the costs and burdens associated with a number of regulatory requirements, and this streamlining would have no negative environmental impacts, and, in some cases, even positive environmental outcomes.

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<sup>1</sup> 82 Fed. Reg. 12,285 (Mar. 1, 2017).

<sup>2</sup> 82 Fed. Reg. at 17,793.

<sup>3</sup> Attached as Appendix A is a list of the Class of ’85 members who support these comments.

<sup>4</sup> Brief descriptions of the numerous regulatory programs addressed in these comments are included in Appendix B.

## II. COMMENTS

### A. EPA Should Streamline Recordkeeping and Reporting Requirements to Eliminate Duplicative Obligations.

EPA should revise certain provisions of the Code of Federal Regulations (“C.F.R.”) to streamline recordkeeping and reporting requirements across the Agency’s various regulatory programs. In numerous cases, EGUs are required to submit the same information to the Agency under multiple programs, resulting in duplicative reporting that provides no environmental benefit at the cost of increased staff time. Specific examples of duplicative reporting requirements that EPA should streamline include the following:

- **Greenhouse Gas (“GHG”) Emissions Reporting.** EPA should exempt from the requirement to submit carbon dioxide (“CO<sub>2</sub>”) emissions data pursuant to the GHG Reporting Rule<sup>5</sup> EGUs that already submit to EPA all information needed to calculate CO<sub>2</sub>e emissions (*e.g.*, CO<sub>2</sub>, nitrous oxide, and methane) pursuant to other rules, such as the Acid Rain Program. For instance, 40 C.F.R. § 98.3(c)(4)(iii)(B) of the GHG Reporting Rule is duplicative of the Acid Rain Program requirement in 40 C.F.R. § 75.64 that EGUs submit to EPA CO<sub>2</sub> mass emissions data. For EGUs subject to these duplicative requirements, submission of this data under the GHG Reporting Rule is superfluous and unnecessary. Eliminating these duplicative requirements would streamline reporting and eliminate a regulatory burden that provides no environmental benefits.
- **Periodic Maximum Achievable Control Technology (“MACT”) Reports.** EPA should streamline duplicative reporting requirements in the National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Industrial, Commercial, and Institutional and Process Heaters (“Boiler MACT”) and Title V regulations. Specifically, EPA should eliminate the requirement to submit annual and biennial reports under the Boiler MACT,<sup>6</sup> where such submissions are duplicative of Title V reports. For example, under the Boiler MACT, periodic reports must include information on whether the source experienced any deviations from an emission limit or operating limit.<sup>7</sup> This requirement is duplicative of the requirement to include in Title V reports information on “[a]ll instances of deviations from permit requirements.”<sup>8</sup> The Class of ’85 urges EPA to streamline these regulations to reduce the regulatory burden on industry and the administrative burden on EPA.
- **Part 60 Summary Reports.** EPA should eliminate the requirement in Part 60<sup>9</sup> to submit information in a summary report that already is submitted pursuant to the Part

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<sup>5</sup> 81 Fed. Reg. 89,188 (Dec. 9, 2016).

<sup>6</sup> See 40 C.F.R. § 63.7550.

<sup>7</sup> 40 C.F.R. § 63.7550(d).

<sup>8</sup> 40 C.F.R. § 70.6(3)(iii).

<sup>9</sup> See 40 C.F.R. § 60.7(d).



75 Electronic Data Reporting (“EDR”) requirements,<sup>10</sup> as the submission of certain information in the summary report is unnecessary and duplicative of the EDR submissions.

- **Part 64 Compliance Assurance Monitoring (“CAM”).** EPA should modify the Part 64 CAM provisions<sup>11</sup> to eliminate requirements that have become unnecessary and outdated in light of subsequent regulations. For example, electrostatic precipitator (“ESP”) power monitoring under CAM<sup>12</sup> has been rendered unnecessary by continuous particulate matter (“PM”) monitoring utilizing either PM Continuous Emissions Monitoring Systems (“CEMS”) or PM Continuous Parametric Monitoring Systems (“CPMS”), and testing required by the Mercury and Air Toxics Standards (“MATS”).<sup>13</sup>

**B. EPA Should Eliminate Monitoring and Testing Requirements That Provide No Environmental Benefits.**

The Class of ’85 urges EPA to eliminate emission monitoring and equipment testing requirements that provide no environmental benefits. Elimination of these requirements would result in significant cost savings for the electric generating industry with no environmental impact. In certain situations, elimination of equipment testing requirements would actually result in *reduced* emissions. Opportunities to eliminate these environmentally unnecessary (and in some cases, environmentally detrimental) requirements exist in numerous CAA programs, including the following:

- **Monitoring Certification and Quality Assurance/Quality Control (“QA/QC”) Redundancies.** EPA should eliminate redundancies between the Part 60 and Part 75 monitoring certification and QA/QC requirements by adding language to Part 60 that provides sources the option to comply only with Part 75 where requirements are duplicative. For example, where Subpart A (*e.g.*, 40 C.F.R. § 60.8 and/or § 60.13), Subpart D, or Subpart GG refer to the appendices in Part 60 for test methods, performance specifications, and QA/QC standards (*e.g.*, Appendix A, B, or F), those references would be replaced by similar references to Part 75.
- **CEMS Certifications on Bypass Stacks.** EPA should reduce the MATS requirements for CEMS certification on bypass stacks in cases where bypass stacks are rarely used (*i.e.*, where bypass stacks operate equivalent to a capacity factor of less than one percent).<sup>14</sup> In these cases, affected sources may be required to bypass *only* for purposes of CEMS certification. For example, one Class of ’85 member installed CEMS (PM, mercury, and hydrogen chloride) on the bypass stacks for two

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<sup>10</sup> See 40 C.F.R. § 75.64.

<sup>11</sup> See 40 C.F.R. §§ 64.1-10.

<sup>12</sup> See 40 C.F.R. § 64.3.

<sup>13</sup> Table 5 to Subpart UUUUU of Part 63.

<sup>14</sup> See 40 C.F.R. § 63.10010(a)(4).

of its units. This company has significantly reduced the use of these bypass stacks, and, in fact, has not used the bypasses since December 2016 and expects very limited use, if any, in the future. Because the company is using the bypass stacks on a very limited basis, it cannot fulfill the CEMS certification requirement unless it runs the stacks specifically for that purpose. In situations like this, the CEMS certification requirement actually results in *increased* emissions because the stacks would not otherwise be in use. Additionally, for some EGUs, the operation of bypass stacks for the sole purpose of CEMS certification could result in emission limit violations. It is illogical that compliance with a monitoring requirement would result in noncompliance with an emission limit. Reducing the frequency of CEMS certification requirements for infrequently used bypass stacks would prevent these unnecessary emissions.

- **Opacity Monitoring Requirements.** EPA should exempt from the Part 60 opacity monitoring requirements<sup>15</sup> units on which a PM CPMS or PM CEMS is installed, as these systems more accurately measure PM emissions than do opacity monitors. In such cases, opacity monitors are unnecessary to assure compliance with PM emissions limits. Relatedly, EPA should edit the text of 40 C.F.R. §§ 60.45(a) and 60.48Da(o)(2) so that EGUs with wet stacks have the option to use opacity monitors as parametric monitors rather than reporting monitors. This is appropriate for EGUs with wet stacks, as opacity monitors are not reliable indicators of PM emissions for facilities with wet scrubbers, as EPA has recognized.<sup>16</sup> Alternatively, EPA could allow EGUs with wet stacks the option of correlating a series of PM stack testing with the opacity monitor results to establish an appropriate compliance limit for the opacity monitor in light of the wet flue gas conditions. Finally, EPA should clarify that Subpart D PM and opacity standards and monitoring requirements apply only when a boiler is operating.<sup>17</sup> Boilers do not generate emissions when they are not combusting fuel, so there is no need for these requirements to apply during these times.
- **Infrequently Operated Reciprocating Internal Combustion Engines (“RICE”).** EPA should reduce the RICE MACT monitoring and testing requirements for non-emergency engines that operate less than 50 hours per year.<sup>18</sup> First, EPA should revise the requirement that testing be completed every 8,760 hours of operation or every three years, whichever comes first,<sup>19</sup> to allow the option that testing be completed (1) based on a reasonable number of hours of engine operation (i.e., 500 hours) or (2) every three years. Eliminating the requirement to perform testing every

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<sup>15</sup> See 40 C.F.R. § 60.45(a); § 60.48Da(o)(2).

<sup>16</sup> See, e.g., 40 C.F.R. § 75.14(b) (exempting EGUs with wet flue gas streams from opacity monitoring requirements).

<sup>17</sup> See 40 C.F.R. § 60.45.

<sup>18</sup> See 40 C.F.R. Part 63, Subpart ZZZZ.

<sup>19</sup> See 40 C.F.R. Part 63, Subpart ZZZZ, Table 3.

8,760 hours or every three years, whichever comes first, would allow for less frequent testing that would have both economic and environmental benefits. It would avoid forcing units to run and burn a significant amount of fuel solely for the purpose of compliance testing. For example, one Class of '85 member estimates that requiring testing once every three years wastes approximately 10,000 gallons of diesel fuel, as the units are forced to run purely for the purposes of testing. Second, the requirement to continuously monitor catalyst inlet temperature and pressure drop is excessive and provides little benefit.<sup>20</sup> These two parameters should be recorded during periodic compliance testing to verify that they are within the allowable ranges during normal operation.

- **Relative Accuracy Test Audits (“RATA”) Testing.** Part 75 requires periodic RATAs of all CEMS.<sup>21</sup> EPA should reduce the number of RATA runs required under Part 75 from nine to three, which would provide just as accurate results with fewer burdens. A study by RMB Consulting & Research, Inc. and the Electric Power Research Institute has found that “if the RATA criteria is [set] met using the results from the first three, four, five or six test runs, performing additional test runs has no impact on the RATA results and consequently no benefit.”<sup>22</sup> See Table 1. Accordingly, if the RATA criteria are satisfied using the results from the first three test runs, no additional test runs should be required, and the RATA should be considered complete. Sources should retain the option to perform additional test runs as necessary, pursuant to the current RATA requirements.

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<sup>20</sup> See 40 C.F.R. Part 63, Subpart ZZZZ, Table 6.

<sup>21</sup> See 40 C.F.R. Part 75, Appendix B; § 75.74.

<sup>22</sup> Russell S. Berry and Stephen K. Norfleet, RMB Consulting & Research, Inc., and Charles E. Dene, Electric Power Research Institute, *The Evolution of Part 75 Performance Test Procedures and Specifications*, at <http://www.rmb-consulting.com/newpaper/tucson/perfspec.html>.

| Table 1: Simulated RATA Data <sup>23</sup> |            |                        |                    |         |                        |                   |
|--------------------------------------------|------------|------------------------|--------------------|---------|------------------------|-------------------|
| Run Number                                 | CEMS Value | Reference Method Value | Standard Deviation | t-value | Confidence Coefficient | Relative Accuracy |
| 1                                          | 103        | 100                    |                    |         |                        |                   |
| 2                                          | 97         | 100                    | 4.24               | 12.71   | 38.12                  | 38.12             |
| 3                                          | 103        | 100                    | 3.46               | 4.303   | 8.61                   | 9.61              |
| 4                                          | 92         | 100                    | 5.32               | 3.182   | 8.46                   | 9.71              |
| 5                                          | 110        | 100                    | 6.82               | 2.776   | 8.47                   | 9.47              |
| 6                                          | 88         | 100                    | 8.08               | 2.571   | 8.49                   | 9.65              |
| 7                                          | 114        | 100                    | 9.35               | 2.447   | 8.64                   | 9.64              |
| 8                                          | 84         | 100                    | 10.53              | 2.365   | 8.81                   | 9.93              |
| 9                                          | 117        | 100                    | 11.56              | 2.306   | 8.89                   | 9.77              |

- **Relative Accuracy Audits (“RAAs”).** EPA should eliminate the requirement to perform quarterly RAAs for units that have converted from hardware CEMS to a software-based predictive emission monitoring system (“PEMS”).<sup>24</sup> This requirement is unnecessary because, unlike a CEMS, a PEMS is a computer model that does not change over time. These units already are required to perform annual RATA testing, which is sufficient to ensure adequate functioning of the PEMS. Performing RAAs on PEMS is a resource and time-intensive process that does not yield any incremental benefit. For example, one Group member has its plant staff maintain old CEMS sample lines, stack probes, and sample pumps so that they can perform the RAA at ground level rather than climb the stacks with a portable analyzer. This effectively defeats the purpose of replacing the old CEMS system.
- **Linearity.** EPA should allow EGUs to perform CEMS linearity and calibrations under Part 75 when units are offline. It takes approximately one hour to perform a linearity, so it is difficult to complete a linearity on combustion turbines that operate for short periods of time. Performance of a linearity while a unit is offline would have no impact on test accuracy, as the CEMS is monitoring calibration gas and not stack gas. Accordingly, this revision would avoid requiring units to operate longer than they otherwise would (and therefore emitting more than they otherwise would) solely to complete a test.

<sup>23</sup> *Id.*

<sup>24</sup> See 40 C.F.R. Part 60, Appendix F, § 5.1.3.

- **Wall Effects Adjustment Factor.** 40 C.F.R. § 75.59(a)(7)(ii)(S) allows for the establishment of a “[c]alculated (site-specific) wall effects adjustment factor determined *during the run*” (emphasis added). However, determining wall effects adjustment factors can take hours, which requires the source owner to maintain the unit at uneconomic loads for longer periods than necessary. EPA should allow EGUs the option to establish a site-specific reference method 2H Wall-Effects adjustment factor under Part 75 so that EGUs no longer need to operate at uneconomic loads for long periods of time just to establish a wall effects adjustment factor.<sup>25</sup>
- **Tuning Requirements for New/Modified Units.** EPA should exempt new and modified units with best available control technology (“BACT”) limits from the initial MATS nitrogen oxides (“NO<sub>x</sub>”) and carbon monoxide (“CO”) tuning requirements.<sup>26</sup> Since these limits are set based on the “best performing” controls, tuning of newly installed equipment is unnecessary.<sup>27</sup>

**C. EPA Should Revise Maintenance Requirements That Provide No Environmental Benefits.**

Numerous CAA programs contain maintenance requirements that are time-consuming and burdensome and yet yield negligible environmental benefits. The Class of ’85 urges EPA to revise these unnecessary maintenance requirements to reduce the regulatory burden on the electric generating industry. Examples of provisions that should be revised include the following:

- **Emergency Engines Under the RICE MACT and New Source Performance Standards (“NSPS”).** The RICE MACT and NSPS limit operation of emergency engines to 100 hours of operation per year for maintenance and readiness testing, 50 of which can be used for non-emergency operation.<sup>28</sup> Additionally, the RICE NSPS requires owners/operators to maintain emergency engines per the manufacturer’s specifications.<sup>29</sup> These requirements have two significant ramifications for owners and operators of emergency engines, while providing negligible environmental benefit.

*First*, owners/operators must spend an unreasonable amount of time tracking the hours of operation of these engines, as well as the reasons for which operation occurred. The time spent on this tracking is grossly disproportionate to the amount of time that these engines operate. For example, one Group member has over 80 small

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<sup>25</sup> See 40 C.F.R. § 75.59(a)(7)(ii)(S).

<sup>26</sup> See 40 C.F.R. § 63.10005(e).

<sup>27</sup> EPA should consider extending this exemption from initial tuning requirements to existing units with controls that have been determined to be equivalent to BACT pursuant to consent decrees or other regulatory program requirements, such as a regional haze state implementation plan.

<sup>28</sup> 40 C.F.R. § 63.6640(f); 40 C.F.R. § 60.4211(f).

<sup>29</sup> 40 C.F.R. § 60.4211(a)(1).

engines (*i.e.*, under 500 horsepower) that are subject to either the RICE MACT or NSPS. On average, these engines each operate approximately 20 hours per calendar year. To document compliance with the hours of operation limit, the company spends an average of six hours per engine, each year, tracking and reporting operations. In other words, for every 20 hours of operating time, the company spends six hours on paperwork—a highly inefficient ratio. Additionally, compliance with the Engine NSPS requirement to maintain emergency engines per the manufacturer’s specifications requires burdensome tracking for facilities that own dozens of certified generators from different manufacturers, all of which have different maintenance procedures and schedules.

*Second*, owners/operators must comply with excessive maintenance requirements for these small, infrequently operated engines. Specifically, the RICE MACT requires owners/operators to perform frequent oil changes or oil analyses,<sup>30</sup> which are unnecessary for infrequently run units and result in the unnecessary and environmentally burdensome disposal of oil. These unnecessary oil changes and oil analyses also are expensive; one Group member estimates that it spends approximately \$700 on annual maintenance for each emergency engine (over \$55,000 annually combined). Additionally, the RICE NSPS requirement to comply with manufacturer specifications can similarly result in unnecessary oil changes,<sup>31</sup> as well as other unnecessary maintenance procedures, on emergency engines that run infrequently.

The Group proposes three solutions to these problems, all of which would significantly reduce the tracking, reporting, and maintenance burdens discussed above, with negligible environmental impact:

- *First*, the Group urges EPA to amend the RICE MACT and NSPS to exempt emergency engines under 500 horsepower. This would (1) eliminate the excessive tracking requirements for run hours and reasons for run; and (2) eliminate the requirement for unnecessary and environmentally detrimental oil changes or oil analyses under 40 C.F.R. § 63.6625(i)-(j). Instead, oil changes would be performed as needed to properly maintain units in light of how much they have run. These changes would result in significant cost savings and drastically reduce administrative burdens, without changing the environmental benefits of the MACT, as these units are very small with low emissions. At a minimum, EPA should exempt emergency engines under 500 horsepower from tracking requirements.
- *Second*, for emergency engines over 500 horsepower that remain subject to the RICE MACT and NSPS, EPA should eliminate the limitation of non-emergency operation to 50 hours per year; instead, EPA should allow these

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<sup>30</sup> 40 C.F.R. § 63.6625(i)-(j).

<sup>31</sup> 40 C.F.R. § 60.4211(a)(1). .

units to operate up to 100 hours per year for maintenance, readiness testing, *and* non-emergency operation (not to include operation as part of a financial arrangement with another entity). This would eliminate the need to track the reasons for which the units operate while ensuring that these units do not operate any more than already is permitted under the current regulatory requirements. Alternatively, EPA should at a minimum exempt these engines from tracking requirements.

- *Third*, EPA should revise the requirement under the RICE NSPS to maintain emergency engines per the manufacturer's specifications to allow EGUs the **option** to develop their own operation and maintenance plans that would allow them an opportunity to streamline their maintenance obligations for their small generators. Exercise of this option would have negligible environmental impact, as owners/operators must properly maintain units, including by performing oil changes or oil analyses when appropriate based on how much the engine has actually run, so that they will be available when needed during emergencies, and because these units run very infrequently.
- **Definition of "Emergency Situation" in RICE MACT and NSPS.** EPA has interpreted the definition of an "emergency situation" under the RICE MACT narrowly to mean "a sudden, unplanned and unforeseen event."<sup>32</sup> Because of this narrow interpretation, companies are incentivized to rent higher-emitting diesel generators rather than rely on onsite back-up generators when power is lost to a facility due to planned maintenance, such as when work on a substation that provides power to a facility must be performed. EPA should define "emergency situation" in the RICE MACT and NSPS to clarify that in situations where power is not available, the operation of on-site emergency engines to provide replacement power would be considered an emergency situation. This would result in reduced emissions, as companies would no longer need to rent high-emitting diesel generators purely to avoid exceeding the 100-hour limitation of non-emergency operation.
- **Oil Change Requirements Under the RICE MACT.** EPA should amend 40 C.F.R. § 63.6625(i) to extend the deadline for performing an oil change from two to 20 business days after receiving an adverse oil analysis result. This would allow sufficient time to resample to confirm an adverse result and avoid unnecessary oil changes, which require the environmentally burdensome disposal of oil.

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<sup>32</sup> See, e.g., Letter from Becky Weber, Director, EPA Region 7 Air and Waste Management Division, to Floyd Gilzow, Director of Member Relations and Public Affairs, Missouri Public Utility Alliance, re: 40 CFR Part 63 National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines; Final Rule Dated March 3, 2010, available at [http://c.ymcdn.com/sites/www.kmunet.org/resource/resmgr/Presentations\\_Misc\\_Docs/EPA%20Response%20to%20MPUA.pdf](http://c.ymcdn.com/sites/www.kmunet.org/resource/resmgr/Presentations_Misc_Docs/EPA%20Response%20to%20MPUA.pdf).

- **Boiler Tune-Ups.** EPA should amend the frequency of required tune-ups under the Boiler MACT to be based on calendar years (*e.g.*, once every calendar years), instead of every 13 months.<sup>33</sup> From a compliance perspective, tracking compliance deadlines based on a calendar year is significantly more manageable than tracking compliance deadlines that do not occur on the same date each year.

#### **D. Additional Recommendations to Reduce Regulatory Burdens.**

The Group urges EPA to make the following revisions to its CAA-related regulations to further streamline regulatory requirements while still protecting the environment:

- **Low-Emitting EGUs Under MATS.** The Group recommends that EPA amend the MATS provisions addressing the demonstration of low-emitting EGU (“LEE”) status to permit use of actual unit operating data, rather than potential maximum operating data.<sup>34</sup> Eligibility for LEE status requires that a source calculate potential annual mercury emissions assuming “maximum potential annual heat input to the unit”<sup>35</sup> or “maximum potential annual electricity generation”<sup>36</sup> times 8,760 hours. This approach employs unreasonable assumptions about unit operation, as using maximum potential heat input or electricity generation vastly overestimates annual mercury emissions because coal-fired EGUs do not operate at maximum capacity constantly for every hour of a calendar year. It would be more accurate to use *actual* data to calculate annual mercury emissions. The Group urges EPA to amend the MATS so that the mercury emission rate result from the 30-day test (as described at 40 C.F.R. § 63.10005(h)(3)) performed during the reporting year would be multiplied by the actual annual heat input to the unit or annual electricity generation (instead of the maximum potential) and reported as part of the semiannual compliance report. This would allow more units to qualify as LEE, which allows for reduced testing obligations but also imposes more stringent mercury emissions limits. Overall, this would alleviate testing and reporting burdens, with no increase in mercury emissions, and could even decrease emissions.
- **Clarification in the MATS Rule.** The Group urges EPA to clarify the reference value to be used in the system integrity checks (“SICs”) required under the MATS.<sup>37</sup> EPA also should clarify or update 40 C.F.R. § 63.10023(b) regarding PM CPMS operating limits to expressly allow for the use of stack concentration or other raw data signals in addition to milliamps to determine site specific operating limits (“SSOL”). Section 63.10023(b), which provides instructions on how to calculate the SSOL from the performance test, lists only milliamps and not stack concentration or other raw

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<sup>33</sup> See 40 C.F.R. § 63.7515(d).

<sup>34</sup> See 40 C.F.R. § 63.10005(h).

<sup>35</sup> 40 C.F.R. § 63.10005(h)(3)(iii)(C)(1).

<sup>36</sup> 40 C.F.R. § 63.10005(h)(3)(iii)(C)(2).

<sup>37</sup> See 40 C.F.R. Part 63, Subpart UUUUU, Appendix A, § 4.1.1.3.



data signals. The omission of stack concentration or other raw data signals from 40 C.F.R. § 63.10023(b) appears to be an oversight. For instance, 40 C.F.R. § 63.10023(a) expressly allows the use of multiple different output values (e.g., milliamps, stack concentration, or other raw data signals) from the PM CPMS during the performance test. Further, Table 7 to Subpart UUUUU lists milliamps, PM concentration, and raw data signals as acceptable outputs to monitor for compliance with the 30 day operating limit. EPA should revise 40 C.F.R. § 63.10023(b) to similarly expressly list stack concentration or other raw data signals in addition to milliamps. This would avoid the regulatory confusion that could occur if regulators view milliamps as the only acceptable output to monitor because it is the only output specifically listed in 40 C.F.R. § 63.10023(b).

- **MATS Residual Risk Review.** The Group strongly recommends that EPA complete the residual risk and technology review for coal-fired power plants covered by the MATS. Section 112(f)(2) of the CAA requires EPA to assess the risk remaining after the implementation of a specific NESHAP. Specifically, within eight years of a final NESHAP, EPA must promulgate an emission standard, if promulgation of such a standard is required in order to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. Because the MATS was finalized and published in 2012, EPA is required to complete this review by 2020. EPA should undertake a rulemaking to fulfil this nondiscretionary statutory obligation.
- **Once in, Always in.** On May 16, 1995, EPA released a memorandum titled “Potential to Emit for MACT Standards-Guidance on Timing Issues.”<sup>38</sup> This guidance document clarified that “facilities that are major sources for [hazardous air pollutants (“HAPs”)] on the ‘first compliance date’ are required to comply permanently with the MACT standard to ensure that maximum achievable reductions in toxic emissions are achieved and maintained.” This interpretation dis-incentivizes changes to major sources that would reduce emissions because these units will always be regulated as major sources. The Group urges EPA to withdraw this guidance document.
- **AP-42 Emission Factors.** EPA has been publishing a compilation of air pollutant factors (AP-42) since 1968.<sup>39</sup> The compilation currently contains emission factors and process information for more than 200 air pollution source categories. The Fifth Edition of AP-42 was published over 20 years ago, in January 1995. While EPA has published some supplements and updates to that edition, the Group encourages EPA to make long-overdue revisions to the AP-42 emission factors. Many of the current factors are based on outdated technology and small sample sizes, which results in

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<sup>38</sup> John S. Seitz, *Potential to Emit for MACT Standards-Guidance on Timing Issues* (1995), <https://www.epa.gov/sites/production/files/2015-08/documents/pteguid.pdf>

<sup>39</sup> R.L. Duprey, *Compilation of Air Pollutant Factors* (1968), [https://www3.epa.gov/ttn/chief/ap42/oldeversions/1st edition/ap42\\_phs 1968.pdf](https://www3.epa.gov/ttn/chief/ap42/oldeversions/1st%20edition/ap42_phs_1968.pdf)

inaccurate estimation of emissions. This impacts permit application development and compliance with reporting requirements. Updating the AP-42 emission factors will increase accuracy and help streamline the permitting process.

- **Ultrasonic Flow Monitors.** The Acid Rain Program establishes requirements for the monitoring, recordkeeping, and reporting of SO<sub>2</sub>, NO<sub>x</sub>, CO<sub>2</sub>, volumetric flow, and opacity data from affected units.<sup>40</sup> These monitoring requirements are performance-based, which means they generally do not require that a source use a particular type of CEMS.<sup>41</sup> However, the regulatory requirements differ depending on the particular type of CEMS utilized. Ultrasonic meters, which measure volumetric natural gas flow rates, are the most accurate type of meter, but are subject to more complicated regulatory requirements. Because ultrasonic monitoring is not explicitly approved under either Appendix D or Appendix E, use of ultrasonic monitors is conditioned upon development and implementation of a QA/QC program for the systems.<sup>42</sup> To ensure regulatory compliance, the ultrasonic meter readings must be compared to a primary standard (AGA/ASME/NIST) meter or to an in-line reference meter that has been tested for accuracy during the previous year.<sup>43</sup> For the in-line reference meter approach, the entity must run three separate tests for three different load levels each with a minimum length of 20 minutes.<sup>44</sup> This means the entity must complete at least nine 20 minute runs within seven consecutive unit operating days.<sup>45</sup> For ongoing QA/QC, this testing must be repeated every four fuel flow meter operating quarters, where an operating quarter is a quarter in which the fuel flow meter has operated for at least 168 partial or full operating hours.<sup>46</sup> Thus, the current regulation disincentivizes installation of the most advanced and modern monitoring technology by imposing significantly more testing requirements. The Class of '85 urges EPA to revise these regulations to update the monitoring systems approved under Appendix D and Appendix E to address the use of ultrasonic meters. This will allow companies to install the best monitoring technology without an increased regulatory burden.

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<sup>40</sup> See 40 C.F.R. § 75.1.

<sup>41</sup> See Part 75 CEMS Field Audit Manual, EPA at 15 (July 16, 2013), [https://www.epa.gov/sites/production/files/2015-05/documents/part\\_75\\_cems\\_field\\_audit\\_manual.pdf](https://www.epa.gov/sites/production/files/2015-05/documents/part_75_cems_field_audit_manual.pdf)

<sup>42</sup> 40 C.F.R. Part 75, Appendix B.

<sup>43</sup> 40 C.F.R. Part 75, Appendix D, § 2.1.5-2.1.6(b).

<sup>44</sup> *Id.* § 2.1.5.2.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* § 2.1.6(a).

### III. CONCLUSION

The Class of '85 appreciates the opportunity to comment on existing regulations and make recommendations regarding their repeal, replacement, or modification. The Group urges EPA to follow the recommendations in these comments, which would alleviate "unnecessary regulatory burdens." Specifically, adoption of the proposed regulatory reforms in these comments would significantly reduce costs associated with recordkeeping, reporting, testing and maintenance, while maintaining, and in some cases improving, environmental protection.

Dated: May 15, 2017

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Debra Jezouit".

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## **Appendix A**

### **CLASS OF '85 REGULATORY RESPONSE GROUP**

**AES Corporation**  
**Alliant Energy Corporation**  
**Arizona Electric Power Cooperative, Inc.**  
**Arkansas Electric Cooperative Corporation**  
**City of Tallahassee**  
**Cleco Corporation**  
**Cogentrix Energy Power Management, LLC**  
**Dairyland Power Cooperative**  
**Dayton Power & Light Company**  
**Entergy Services, Inc.**  
**Florida Municipal Electric Association**  
**Florida Municipal Power Agency**  
**Gainesville Regional Utilities**  
**Great River Energy**  
**Hawaiian Electric Company, Inc.**  
**Indianapolis Power & Light Company**  
**JEA**  
**Lakeland Electric**  
**Louisville Gas & Electric/Kentucky Utilities**  
**National Grid**  
**NextEra Energy, Inc.**  
**OGE Energy Corp.**  
**Orlando Utilities Commission**  
**PowerSouth Energy Cooperative**  
**Public Service Company of New Mexico**  
**Salt River Project**  
**Talen Energy**  
**Tampa Electric Company**  
**Westar Energy**  
**Western Farmers Electric Cooperative**  
**Xcel Energy Inc.**

## Appendix B

| <b>Rule</b>        | <b>C.F.R.</b>                    | <b><i>Federal Register</i></b>                                                                               | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acid Rain Program  | 40 C.F.R. Parts 72-78            | 58 Fed. Reg. 3,590 (Jan. 11, 1993); 58 Fed. Reg. 15,634 (Mar. 23, 1993); 62 Fed. Reg. 55,460 (Oct. 24, 1997) | The Acid Rain Program, established under Title IV of the Clean Air Act (“CAA”), requires electric generating units (“EGUs”) to reduce emissions of sulfur dioxide (“SO <sub>2</sub> ”) and nitrogen oxides (“NO <sub>x</sub> ”), the primary precursors of acid rain.                                                                                                                                                                                                |
| Boiler MACT        | 40 C.F.R. Part 63, Subpart DDDDD | 80 Fed. Reg. 72,790 (Nov. 20, 2015)                                                                          | The Boiler Maximum Achievable Control Technology (“MACT”) rule sets national emission standards for hazardous air pollutants (“NESHAPs”) reflecting MACT for industrial boilers, commercial and institutional boilers, and process heaters that are located at major sources ( <i>i.e.</i> , sources that emit or have the potential to emit above a certain threshold of hazardous air pollutants (“HAPs”) per year) for various HAPs under Section 112 of the CAA. |
| CAM Rule           | 40 C.F.R. Part 64                | 62 Fed. Reg. 54,900 (Oct. 22, 1997)                                                                          | The Compliance Assurance Monitoring (“CAM”) Rule establishes enhanced monitoring and compliance certification requirements for major stationary sources that are required to obtain Title V operating permits.                                                                                                                                                                                                                                                       |
| GHG Reporting Rule | 40 C.F.R. Part 98                | 74 Fed. Reg. 56,260 (Oct. 30, 2009); 81 Fed. Reg. 89,188 (Dec. 9, 2016)                                      | The Greenhouse Gas (“GHG”) Reporting Rule requires monitoring and reporting of GHG emissions from sources across multiple sectors of the economy, including EGUs, that emit above a certain threshold of carbon dioxide equivalent per year.                                                                                                                                                                                                                         |
| MATS               | 40 C.F.R. Part 63, Subpart       | 77 Fed. Reg. 9,304 (Feb.                                                                                     | The Mercury and Air Toxics Standards (“MATS”) rule sets NESHAPs for EGUs for various HAPs, including mercury,                                                                                                                                                                                                                                                                                                                                                        |

|                 |                                           |                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------|-------------------------------------------|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 | UUUUU                                     | 16, 2012)                           | under Section 112 of the CAA.                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Part 60         | 40 C.F.R. Part 60                         | 36 Fed. Reg. 24,877 (Dec. 23, 1971) | Part 60 establishes standards of performance for new stationary sources, including general provisions under Subpart A; standards of performance for fossil fuel-fired steam generators under Subpart D; and standards of performance for electric utility steam generating units under Subpart Da. Part 60 also contains appendices that establish testing procedures that must be followed to establish compliance with the requirements of the various subparts. |
| RICE MACT       | 40 C.F.R. Part 63, Subpart ZZZZ           | 78 Fed. Reg. 6,674 (Jan. 30, 2013)  | The Reciprocating Internal Combustion Engine (“RICE”) MACT sets NESHAP reflecting MACT for RICE located at major or area sources for various HAPs under Section 112 of the CAA.                                                                                                                                                                                                                                                                                    |
| RICE NSPS       | 40 C.F.R. Part 60, Subparts IIII and JJJJ | 78 Fed. Reg. 6,674 (Jan. 30, 2013)  | The RICE New Source Performance Standards (“NSPS”) set performance standards for emissions from new, modified, and reconstructed stationary compression ignition internal combustion engines and stationary spark ignition internal combustion engines under Section 111(b) of the CAA.                                                                                                                                                                            |
| Title V Program | 40 C.F.R. Parts 70 and 71                 | 57 Fed. Reg. 32,250 (July 21, 1992) | Title V of the CAA requires major sources and some non-major sources to obtain and operate in compliance with an operating permit that contains all applicable CAA requirements for the source.                                                                                                                                                                                                                                                                    |

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**Subject:** Dudley-Peacock paper attached  
SDudley+MPeacock\_Regulatory-Science-and-Policy-6-30-2017.pdf  
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# THE GEORGE WASHINGTON UNIVERSITY

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WASHINGTON, DC

Working Paper<sup>1</sup>

June 30, 2017

## Improving Regulatory Science A Case Study of the National Ambient Air Quality Standards

Susan E. Dudley, Director, & Marcus Peacock<sup>2</sup>

The George Washington University Regulatory Studies Center

### Abstract

This paper explores the motivations and institutional incentives of participants involved in the development of regulation aimed at reducing health risks, with a goal of understanding and identifying solutions to what the Bipartisan Policy Center has characterized as “a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, [that] is at the root of the stalemate and acrimony all too present in the regulatory system today.” We focus our analysis with a case study of the procedures for developing National Ambient Air Quality Standards under the Clean Air Act, and attempt to identify procedural approaches that bring greater diversity (in data, expertise, experience, and accountability) into the decision process.

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<sup>1</sup> This working paper, which has been submitted to the *Supreme Court Economic Review*, reflects the views of the authors and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center’s policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

<sup>2</sup> Susan E. Dudley is Director of the GW Regulatory Studies Center and Distinguished Professor of Practice in the Trachtenberg School of Public Policy and Public Administration. Marcus Peacock is Executive Vice President at Business Roundtable. The authors are grateful for constructive comments from Sydney Allen, Art Fraas, George Gray, Brian Mannix, John McGinnis, and Sofie Miller, as well as feedback from participants at conferences of the Society for Benefit Cost Analysis, the Society for Risk Analysis, and the George Mason Law & Economics Center.



## Regulatory Science and Policy

Regulations intended to address public health and environmental risks depend heavily on scientific information. These regulations are often the subject of heated debate, involving accusations of “politicized science,” “advocacy science,” and “junk science.”<sup>3</sup> While it is legitimate to want to protect the integrity of scientific findings, more often than not, these policy debates center on issues that science must inform, but cannot decide.

No one is immune to the temptation to spin science to advance a pre-determined policy goal. However, masquerading policy preferences as “science” can be extremely harmful. At its worst, scientists and policymakers work, wittingly or unwittingly, in an unholy alliance to support harmful political preferences in the name of “science.” Perhaps the most notorious example in the United States is the extent to which some scientists in the 19<sup>th</sup> century declared certain human races inherently “inferior.” This “evidence” was, in turn, used by politicians to justify, and defend, race-based slavery.<sup>4</sup> Fortunately, the costs of “politicized science” in the United States today are less severe than mass human enslavement, but they can still have significant adverse effects on public policies as well as diminish the integrity of scientific advice.

While there is extensive media coverage of “politicized science” related to public disagreements regarding regulatory issues that have a strong scientific component, such as genetically-modified organisms or climate change, the examination of how science may be politicized inside federal regulatory decision-making processes has been largely limited to academia and the scientific community.<sup>5</sup> In particular, while attempts by advocates of policies to improperly shape science have been widely presented in the media, in everything from main stream news reports<sup>6</sup> to the HBO series *Mad Men*,<sup>7</sup> there has been much less examination of the role of scientists improperly attempting to shape policy decisions. Yet the latter problem can be just as serious. As former Assistant Administrator of the US Environmental Protection Agency, Milton Russell, has noted, while government scientists need to be protected from “influence over what they *find and report*,” “policy-makers must be protected from policy analysts or scientists telling them what

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<sup>3</sup> See, for example, Jason Scott Johnston, ed. *Institutions and Incentives in Regulatory Science*. Lexington Books (2012)

<sup>4</sup> See, for instance, the work of anthropologist Henry Hotze on behalf of the Confederate States of America in Lonnie A. Burnett, *Henry Hotze: Confederate Propagandist*, University of Alabama Press: Tuscaloosa, AL (2008).

<sup>5</sup> See, for instance, Jake C. Rice, “Food for Thought: Advocacy science and fisheries decision-making,” *ICES Journal of Marine Science*, 68(10) (2011), pp. 2007-2012.

<sup>6</sup> See, for instance, a discussion of how politicians from both major parties attempt to spin science in Sheryl Gay Stolberg, “Obama Puts His Own Spin on Mix of Science with Politics,” *The New York Times*, March 9, 2009.

<sup>7</sup> See, for instance, the discussion of the manipulation of the public regarding the health effects of tobacco on behalf of tobacco companies in “Smoke Gets in Your Eyes.” *Mad Men: Season One*. Writ. Matthew Weiner. Dir. Alan Taylor. AMC, 2007.

they should *decide*, but open to information about what the consequences of alternative decisions are likely to be.”<sup>8</sup>

This paper examines two types of politicized science that can infect policymaking inside regulatory agencies. The first is when scientists, intentionally or unintentionally, insert, but do not disclose, their own policy preferences in the scientific advice they provide government decision-makers. Such “hidden policy judgments” are a form of “advocacy science.”<sup>9</sup> The second is when scientists and/or policymakers conflate scientific information and nonscientific judgments to make a policy choice, but then present that decision as being solely based on science. It is this tendency to “camouflag[e] controversial policy decisions as science” that Wagner called a “science charade”<sup>10</sup> and it can be particularly pernicious. For instance, a 2009 Bipartisan Policy Center (BPC) 2009 report, *Improving the Use of Science in Regulatory Policy*, concluded that “a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.”<sup>11</sup> Both of these problems, hidden policy judgments and the science charade, can be the result of officials falling prey to the “is-ought fallacy”: incorrectly mixing up positive information about what “is” with normative advice about what “ought to be.”

This paper focuses on the problems of hidden policy judgments and the science charade inside federal regulatory agencies. It examines why these are problems, the institutional incentives that contribute to them, and possible remedies. After describing what we mean by hidden policy judgments and the science charade, and describing the “is-ought fallacy,” we illustrate these problems by examining the incentives and behavior of participants in the development of national ambient air quality standards (NAAQS) under the Clean Air Act.<sup>12</sup> The paper concludes with ten recommendations for changing those incentives.

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<sup>8</sup> Milton Russell, “Lessons from NAPAP,” *Ecological Applications*, 2(2), 1992, p. 108.

<sup>9</sup> “Advocacy science” is an elusive term and can, for instance, include the activity of scientists seeking more federal funding for research. For the purposes of this paper the term is defined as when a policy preference is presented in the form of scientific advice. For a discussion of advocacy science see Deborah Runkle, Mark S. Frankel ed., “Advocacy in Science: Summary of a Workshop convened by the American Association for the Advancement of Science,” 1 May 2012, pp. 2-3.

<sup>10</sup> Wagner, W.E. The Science Charade in Toxic Risk Regulation. Columbia Law Review. 1995 Nov;95(7): 1614; 29.

<sup>11</sup> Bipartisan Policy Center. *Improving the Use of Science in Regulatory Policy*. Washington (DC): Bipartisan Policy Center; 2009;10. Available at: <http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf> “BPC”

<sup>12</sup> The Clean Air Act, 42 U.S.C. § 7408 Available at: <http://www.gpo.gov/fdsys/pkg/USCODE2008-title42/pdf/USCODE-2008-title42-chap85.pdf>

## The Politicization of Science

Science is rarely sufficient for making policy decisions for two reasons. First, while science is essential for understanding the positive question of *what is*, or predicting what outcomes might obtain under different scenarios, it is not determinative for the normative decisions regarding what *ought to be*.<sup>13</sup> Along these lines, in 1983 the National Research Council (NRC) of the National Academy of Sciences described the following conceptual framework for making regulatory decisions regarding health, safety and environmental risks:

Regulatory actions are based on two distinct elements, risk assessment... and risk management. Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.<sup>14</sup>

In other words, regulatory decisions can be split conceptually into two phases. The risk assessment phase provides science-based information regarding what we know about a risk (positive information regarding *what is*). However, risk assessment is a necessary, but rarely sufficient, input for deciding how the government should regulate a risk. That requires a second phase, risk management, to determine what *ought to be*. Sound policy decisions regarding risk management typically need to consider a host of non-scientific factors such as economic feasibility, legal constraints, ethical considerations, and the existence of other public policies that may address, or exacerbate, the risk, to name just a few.

### Hidden policy judgments in risk assessments

Unfortunately, in practice there is not a clear distinction between scientific and policy decisions in the regulatory process. First, when it comes to risk assessment, scientists will never have complete information to predict outcomes with certainty, so analysts rely on what the NRC calls “risk assessment policy”—assumptions, judgments, and rules of thumb—to guide the use of scientific information in analyses that inform policy in the face of uncertainty. The NRC puts it this way:

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<sup>13</sup> See John Neville Keynes, *The Scope and Method of Political Economy*, Fourth Edition., Batoche Books: Kitchener, Ontario (1999), p. 22.

<sup>14</sup> National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. *Risk Assessment in the Federal Government: Managing the Process*. 1983. Washington D.C.: National Academies Press, p. 3. This document is also commonly known as the “Red Book.”

In each step [of the risk assessment process], a number of decision points (components) occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges, and we have used the term risk assessment policy to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions.<sup>15</sup>

Thus, the risk assessment phase itself embeds judgments that need to be made to produce a result that scientists can give to policymakers; and these judgments, intentionally or not, can bias the ultimate advice provided to decision-makers and the public.

This fuzziness between science and policy choices is not unique to health and safety regulations. In 1972 Alvin Weinberg pointed out, “Many of the issues which arise in the course of the interaction between science or technology and society—e.g., the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science—hang on the answers to questions which can be asked of science and yet which cannot be answered by science.”<sup>16</sup> To describe such questions, Weinberg coined the term “trans-science.” Figure 1 below illustrates the relationship between pure scientific inputs and policy decisions, and the role of “trans-science” and judgment in interpreting and presenting evidence relevant to policy. “Risk assessment policy” includes various judgments, including: which science is considered; how individual studies are weighed and combined; when competing theories are considered appropriately supported for inclusion; which models to use; and in general, what to do in the face of scientific uncertainty. It also guides the way in which risks are characterized and communicated.<sup>17</sup>

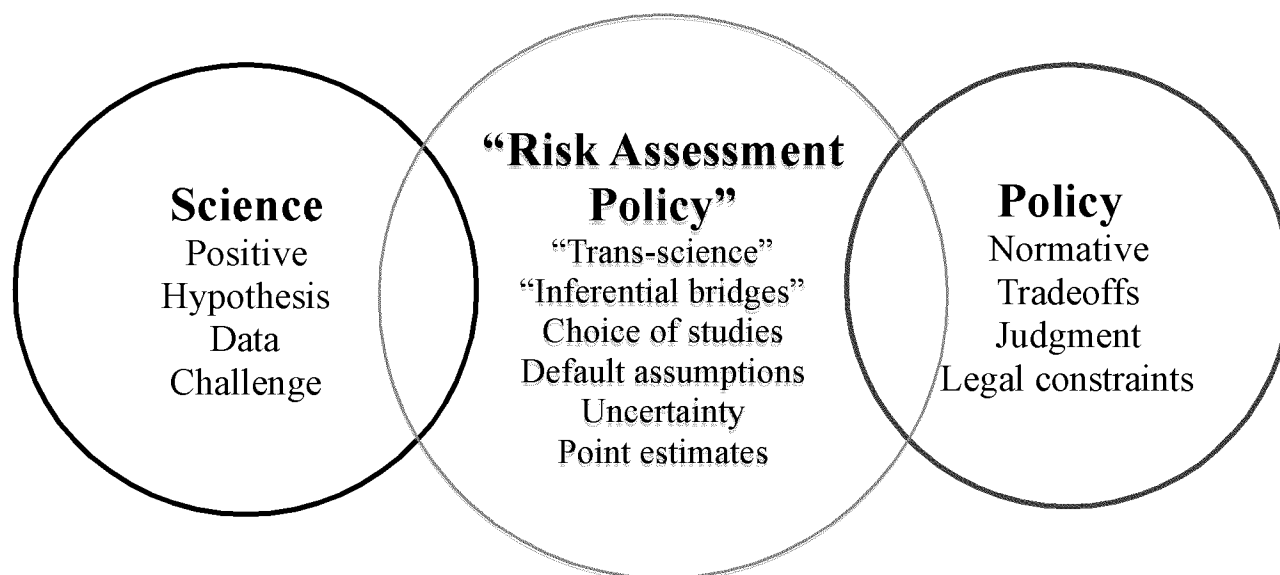
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<sup>15</sup> National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. *Risk Assessment in the Federal Government: Managing the Process*. 1983. Washington D.C.: National Academies Press, p. 3.

<sup>16</sup> Alvin M. Weinberg. "Science and Trans-Science." *Science* 177.4045 (1972): 211. Print. “I propose the term trans-scientific for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science... Scientists have no monopoly on wisdom where this kind of trans-science is involved....”

<sup>17</sup> Dudley, SE & Gray, GM. “Improving the Use of Science to Inform Environmental Regulation,” in *Institutions and Incentives in Regulatory Science*, Lexington Books, Jason Johnston ed. (2012)

**Figure 1. Science, Policy, and “Risk Assessment Policy”**



Based on Dudley and Gray, “Improving the Use of Science to Inform Environmental Regulation,” in *Institutions and Incentives in Regulatory Science*, Lexington Books, Jason Johnston ed. (2012)

Policymakers and the public are often unaware of the influence of these risk assessment policy choices or the existence of alternative choices that are equally plausible. Instead, assessments often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but the reliance on biased inferences and assumptions for handling that uncertainty.<sup>18</sup> As noted above, this is a problem of hidden policy judgments. While some judgment is necessary to translate scientific evidence into risk assessment, current risk assessment policies are not transparent, and lead to distortions in risk estimates and false precision in the presentation of scientific information.<sup>19</sup> These practices obscure the boundary between science and policy, and contribute to the politicization of science through biased science advice.

Former EPA scientist Robert T. Lackey cautions against this problem, which he calls “normative science”:

<sup>18</sup> For example, EPA’s “Risk Assessment Principles and Practices” document states: “[s]ince EPA is a health and environmental protective agency, EPA’s policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. This policy position prompts risk assessments to take a more ‘protective’ stance given the underlying uncertainty with the risk estimates generated.” (USEPA 2004, 13-14)

<sup>19</sup> Gray, G. & Cohen, J. “Rethink Chemical Risk Assessment.” *Nature*, 2012 Sep; 489. P. 27.: “the problem is the EPA’s use of assumptions that it claims are ‘public health protective,’ which err on the side of overstating risk when data are lacking.... Such inflated risk estimates can lead to overly stringent regulations and can scramble agency priorities because the degree of precaution differs across chemicals.”

Science should be objective and based on the best information available. Too often, however, scientific information presented to the public and decision-makers is infused with hidden policy preferences. Such science is termed normative, and it is a corruption of the practice of good science. Normative science is defined as “information that is developed, presented or interpreted based on an assumed, usually unstated, preference for a particular policy choice.”<sup>20</sup>

Normative science can be masked by presentations that are not transparent. For example, in its 2011 evaluation of EPA’s Integrated Risk Information System (IRIS) assessment for formaldehyde, the National Academy of Sciences raised concerns about recurring “problems with clarity and transparency of the methods”:

In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the [reference dose] RfCs and unit risk estimates.<sup>21</sup>

### **When risk management becomes a science charade**

While embedded policy judgments raise concerns of hidden bias in the *risk assessment* phase of a rulemaking, policy judgments couched as “science” can raise similar problems in the *risk management* phase.

While there should be a clear distinction in the minds of scientists and policymakers between describing what “is” and deciding what “ought to be,” the two are sometimes unintentionally, or intentionally, conflated when the ultimate policy decision is presented as dictated solely by “the science.” We adopt the phrase “science charade”<sup>22</sup> to describe the camouflaging of controversial policy decisions as science.

Scientists and/or policymakers create a science charade by describing a policy decision in purely scientific (or scientific sounding) terms without revealing the trans-science and policy factors that played a role in the decision. For instance, in 1982, EPA faced a decision whether to regulate formaldehyde under the Toxic Substances Control Act. In order to regulate, the Administrator

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<sup>20</sup> Lackey, Robert T. “Normative Science.” *Terra Magazine*. Oregon State University. 2013;8(2).

<sup>21</sup> Committee to Review EPA’s Draft IRIS Assessment of Formaldehyde; National Research Council. *Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde*. Washington (DC): National Academy of Sciences; 2011: 4. Available at: [http://www.nap.edu/catalog.php?record\\_id=13142](http://www.nap.edu/catalog.php?record_id=13142)

<sup>22</sup> See Wendy E. Wagner, “The Science Charade in Toxic Risk Regulations,” *Columbia Law Review*, 95:7 (November 1995), pp. 1613-1723.

had to find “a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings.”<sup>23</sup> Such a decision inherently involves policy judgments regarding the interpretation of the terms “reasonable” basis, “significant” risk and “serious or widespread harm.” Yet, in presenting the issue to the Administrator of EPA, the Assistant Administrator for Pesticides and Toxic Substances couched the decision as a purely scientific judgment:

(a) formaldehyde is a carcinogen in the rat by the inhalation route; (b) its carcinogenic potential appears to vary significantly with species and route; (c) under certain exposure conditions it could present some carcinogenic risk to humans; and (d) given available data the risk estimates suggest that certain populations may experience a carcinogenic risk - albeit low - due to formaldehyde exposure. However, because of the nature of the toxicology data and the unreliability in the exposure data one cannot reasonably conclude, at this time, that formaldehyde poses a significant risk among the U.S. population.<sup>24</sup>

Scientists can unwittingly impose, or intentionally foist, science charades on decisionmakers by hijacking risk management decisions. Policymakers can create science charades on their own (as in the example above), or scientists and policymakers may cooperate in disguising value-laden decisions as the necessary result of “the best science.” Regardless, the science charade results in similar harms as hidden policy judgments in risk assessments: the public is cheated of sound and open policy making and the integrity of science advice is weakened.

### Falling prey to the “is-ought” fallacy

As noted above, science describes what “is” but it cannot solely determine what “ought to be.” Both hidden policy judgments in risk assessments and science charades result from incorrectly mixing up positive information about what “is” with normative advice about what “ought to be.” These errors are examples of the “is-ought fallacy.”<sup>25</sup> This fallacy, first identified by philosophers David Hume and G.E. Moore in the 18th century, happens when a prescription is erroneously embedded in, or directly follows, a description, as if one automatically follows from the other. For instance, the statement “ambient carbon dioxide concentrations are increasing, therefore we must stop burning fossil fuels” may or may not be good public policy but the latter policy decision does not necessarily follow from the former scientific fact. As some scientists

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<sup>23</sup> 15 USC §2603(f)

<sup>24</sup> Nicholas A. Ashford, C. William Ryan, Charles C. Caldart, [A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking](#), 7 Harv. Envtl. L. Rev. (1983), pp. 327-328 excerpting Memorandum from John Todhunter to Anne Gorsuch dated 10 February 1982.

<sup>25</sup> Also called the “naturalistic fallacy,” the “positive-normative fallacy,” Hume’s Law, and Hume’s Guillotine.

have noted, only “in the most trivial of decision contexts, where there is no immediate disagreement about relevant facts, values or decision options, can a fact dictate an action.”<sup>26</sup>

This fallacy is not unique to science. It “is common and has been the source of many mischievous errors”<sup>27</sup> confounding diverse areas of study and decision making.<sup>28</sup> However, it can be particularly pernicious when it influences government regulations that affect the lives of millions of people and the allocation of significant resources. Both scientists and policymakers may fall prey, willfully or not, to the is-ought fallacy.

Scientists and policymakers may intentionally invoke the is-ought fallacy, although for different reasons. Scientists may wish to influence policymakers by subtly absorbing nonscientific assumptions in their risk assessments or in descriptions of what “is” so that it appears there is no better risk management alternative than the one they prefer. Likewise, decisionmakers, such as political appointees, who may fear criticism of a particular decision can muddle descriptions of “is” with assumptions regarding what “ought to be” in the risk management phase of rulemaking and claim that “science” dictated the outcome. In both cases, the fallacy allows scientists and/or policymakers to create a science charade by dressing up a policy decision and disguising it in a lab coat.

### **The harms of politicized science and the example of NAAQS**

The process by which EPA sets National Ambient Air Quality Standards (NAAQS) for “criteria pollutants”<sup>29</sup> under the Clean Air Act illustrates some of the perverse incentives involved in developing regulations, which can encourage biased science advice and a science charade. The NAAQS process is particularly worth examining, because on the one hand it is held up by some as an ideal by which all science-based rulemaking should be developed,<sup>30</sup> but on the other, NAAQS decisions are among the most controversial of EPA policies. Each of the last three

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<sup>26</sup> Daniel Sarewitz, “Science Advocacy is an Institutional Issue, Not an Individual One,” Background Paper for the AAAS Consortium for Science, Policy and Outcomes, Workshop on Advocacy in Science, January 2012, p. 4.

<sup>27</sup> See John Neville Keynes, *The Scope and Method of Political Economy*, Fourth Edition., Batoche Books: Kitchener, Ontario (1999), p. 22.

<sup>28</sup> See, for instance, James A. Davis, “The ‘Is-Ought’ Fallacy and Musicology: The Assumptions of Pedagogy,” *Philosophy of Music Education Review*, Vol. 5, No. 1 (Spring, 1997), pp. 25-32

<sup>29</sup> The Clean Air Act, 42 U.S.C. § 7408 (a)(1) identifies six “criteria pollutants”: particulate matter, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead. Available at: <http://www.gpo.gov/fdsys/pkg/USCODE2008-title42/pdf/USCODE-2008-title42-chap85.pdf>

<sup>30</sup> Wagner, W. “Science in Regulation: A Study of Agency Decision making Approaches” (referring to the NAAQS development process as “the equivalent of a five-star process for incorporating science into regulatory policy.”) 2013: 29. Available at: <http://acus.gov/report/science-regulation-final-report>



presidents has taken the highly unusual step of publicly and personally intervening in EPA's regulatory decisions.<sup>31</sup>

Biasing science advice or framing issues as resolvable solely by science threatens the credibility of the scientific process and damages resulting regulatory policy. Many of those involved in regulatory decisions have incentives to hide rather than reveal the uncertainty in assessments of risk<sup>32</sup> and to dismiss and denigrate dissenting views.<sup>33</sup> Key policy choices, disguised as science, rest with technical staff; meanwhile, political appointees charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by the science.

When questions involving policy judgment and values are falsely characterized as scientific, a small number of people have disproportionate influence on the information that is used and how it is characterized, leading to decisions that are not as accountable or as transparent as they should be.<sup>34</sup> This is exacerbated by the adversarial nature of rulemaking, by the reluctance of courts to review scientific findings, and by group dynamics that discourage differences of opinion, mask uncertainty, and give short shrift to alternative perspectives.

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<sup>31</sup> EPA's 1997 standards for ozone and fine particles were debated extensively at the cabinet level and, on issuance of the final regulations, President Clinton took the unprecedented step of writing a public memorandum to the EPA Administrator on "Implementation of Revised Air Quality Standards for Ozone and Particulate Matter," to "ensure that the new standards are implemented in a common sense, cost-effective manner." Available at: <http://www.gpo.gov/fdsys/pkg/WCPD-1997-07-21/pdf/WCPD-1997-07-21-Pg1080.pdf> (See Fraas 2011 at 81-85 for an insider's account of the 1997 deliberations.) In 2008, EPA again faced objections from other agencies, as well as from state and local governments, when it proposed to revise the ozone standard. President George W. Bush was called in to settle the dispute, following the rarely used section 7 of E.O. 12866 regarding the resolution of conflicts. He decided the dispute over the appropriate form of the welfare standard by directing EPA Administrator Stephen Johnson to set it at a level identical to the primary standard. Available at: [http://www.reginfo.gov/public/postreview/Steve\\_Johnson\\_Letter\\_on\\_NAAQs\\_final\\_3f3-08\\_2.pdf](http://www.reginfo.gov/public/postreview/Steve_Johnson_Letter_on_NAAQs_final_3f3-08_2.pdf) In 2011, the President intervened again. EPA was poised to revise the ozone standard amid strong objections from other parts of the government and the regulated community, when President Obama took the unusual step of "request[ing] that Administrator Lisa Jackson withdraw the draft ozone NAAQS" from interagency review. Available at: <http://www.whitehouse.gov/the-press-office/2011/09/02/statement-president-ozone-national-ambient-air-quality-standards>. This is the only time during President Obama's administration that the White House has returned a regulation to an agency.

<sup>32</sup> According to Wagner, "It would seem that such science-based mandates not only invite, but actually compel the science charade due to the threat of reversal if an agency frankly acknowledges the inherent scientific uncertainties and its requisite retreat to economic, technological, and other policy considerations in reaching a final, quantitative standard." Wagner 1995 at 1668.

<sup>33</sup> For example, see posts by the Center for Progressive Reform (<http://www.progressivereform.org/13RulesOzone.cfm>) and the Center for Regulatory Solutions (<http://centerforregulatoryolutions.org/will-epas-ozone-ambitions-reveal-more-collaboration-with-green-groups/>)

<sup>34</sup> Eisenhower warned in his farewell address, "Yet, in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite."

Using the NAAQS as a case study, the next section explores the procedures for developing regulations and the institutional incentives that may encourage the is-ought fallacy and contribute to politicized science through hidden policy judgments and the science charade.

## Participants in the Rulemaking Process, their Motives & Behavior

The development of regulation in the United States involves several steps and numerous parties. First, Congress must pass and the President must sign legislation authorizing regulation. Legislation addressing health and environmental risks generally expresses broad goals and objectives, but leaves fact-finding and the details of implementation to executive branch agencies, such as EPA.<sup>35</sup> Regulatory agencies then develop draft proposed regulations consistent with the language in the enabling legislation and according to procedures mandated by both Congress and the President.<sup>36</sup> In particular, the Administrative Procedure Act requires regulatory agencies to notify the public and seek comment on proposed regulations, and to base final regulations on information in the rulemaking record.<sup>37</sup> This notice-and-comment process guarantees interested parties (those affected by potential regulation, non-governmental organizations, and others) an opportunity to present views and information on proposed regulations.<sup>38</sup> Additionally, since 1981, presidents have required agencies to conduct regulatory impact analyses (RIAs) of economically significant regulations, and to subject them to interagency review through the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.<sup>39</sup> Congress has an opportunity to fast-track a joint resolution to disapprove a final regulation after it is published,<sup>40</sup> and regulations are also subject to judicial review (allowing affected parties to sue to have regulations overturned by the courts).<sup>41</sup> Throughout the rule development process and beyond, media will also track and report on regulations and any controversies that may arise.

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<sup>35</sup> Schoenbrod, David. *Power without Responsibility: How Congress Abuses the People through Delegation*. Yale University Press. 1995.

<sup>36</sup> Dudley, S.E. & Brito, J. *Regulation: A Primer*. Washington, DC: The George Washington University Regulatory Studies Center and Mercatus Center, George Mason University; 2012.

<sup>37</sup> Administrative Procedure Act (5 U.S.C. Subchapter II) Available at: <http://www.archives.gov/federal-register/laws/administrative-procedure/>

<sup>38</sup> Balla, S.J. "Public Commenting on Federal Agency Regulations: Research on Current Practices and Recommendations to the Administrative Conference of the United States." Washington (DC) 2011. Available at: <http://www.acus.gov/sites/default/files/documents/Consolidated-Reports-%2B-Memoranda.pdf>

<sup>39</sup> See Executive Orders 13563 and 12866 governing regulatory analysis and oversight. Available at: [http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563\\_01182011.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo13563_01182011.pdf)

<sup>40</sup> The Congressional Review Act of 1996 (5 U.S.C. § 801-808) Available at: <http://www.archives.gov/federal-register/laws/congressional-review/>.

<sup>41</sup> Dudley, S.E. & Brito, J. 2012.

The behavior of each party in the regulatory development process is influenced by these institutional structures and constraints, and the incentives they provide, as a case study of the NAAQS development process illustrates.

### Authorizing Legislation

The Clean Air Act of 1970 (P.L. 91-604) directed the newly created Environmental Protection Agency to issue NAAQS for each pollutant for which the Department of Health, Education, and Welfare had already issued air quality criteria, and for widespread air pollutants identified in the future that reasonably may be expected to endanger public health or welfare.<sup>42</sup>

The Act directed the EPA Administrator to set “primary,” or health-based, NAAQS at levels that are “requisite to protect the public health ... allowing an adequate margin of safety,”<sup>43</sup> based on “air quality criteria [that] shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities.”<sup>44</sup> It further required the Administrator to set “secondary” (welfare-based) standards based on these criteria at a level “requisite to protect the public welfare from any known or anticipated adverse effects.”<sup>45</sup>

Amendments to the Clean Air Act in 1977 (P.L. 95-95) required the Administrator to conduct a “thorough review of the criteria...and promulgate such new standards as may be appropriate,” at least every five years.

In 2001 the Supreme Court confirmed EPA’s interpretation that, when it sets primary standards, the statutory language precludes consideration of the costs of achieving the standard.<sup>46</sup> Thus the Clean Air Act itself, at least in this reading, encourages the is-ought fallacy by implying that scientific evidence is sufficient to resolve such normative questions as what is “requisite to protect public health,” or an “adequate margin of safety.”<sup>47</sup>

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<sup>42</sup> For a thorough review of the history of NAAQS, see Bachmann, John. “Will the Circle Be Unbroken: A History of the U.S. National Ambient Air Quality Standards.” *Journal of the Air & Waste Management Association*. Volume 57, Issue 6, 2007. He finds, “Even a cursory look at the history of the NAAQS and air pollution shows that developments are subject to what is sometimes called big “P” (i.e., partisan) and little “p” (e.g., interagency or office) politics and all of the changing societal, economic, cultural, and other influences related to a particular time and place.” Bachmann, 2007: 655.

<sup>43</sup> The Clean Air Act, 42 U.S.C. § 7408 (b)(1)

<sup>44</sup> The Clean Air Act, §108(a)(2)

<sup>45</sup> The Clean Air Act, 42 U.S.C. § 7408 (b)(2)

<sup>46</sup> *Whitman v. American Trucking Associations, Inc.*, 531 U.S. 457 (2001) 99-1426. 175 F.3d 1027 and 195 F.3d 4, affirmed in part, reversed in part, and remanded.

<sup>47</sup> An amicus brief in this case, signed by a bipartisan group of 42 prominent economists, including five Nobel Laureates, argued: “We believe that it would be imprudent for the EPA to ignore costs totally. Not considering costs makes it difficult to set a defensible standard, especially when there is no threshold level below which

According to Schoenbrod:

The legislative history and reality made clear that EPA was not to set the ambient standards at zero. So EPA would necessarily have to leave some threat to health. The statute evaded the question of how much. The evasion was intentional. As the author of the Clean Air Act, Senator Edmund Muskie, later admitted, "[o]ur public health scientists and doctors have told us that there is no threshold, that any air pollution is harmful. The Clean Air Act is based on the assumption, although we knew at the time it was inaccurate, that there is a threshold. When we set the standards, we understood that below the standards that we set there would still be health effects."<sup>48</sup>

The statutory framing makes it much more difficult to follow the Bipartisan Policy Center's first recommendation that "when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy."<sup>49</sup>

While the Act left the decision for setting NAAQS to "the judgment of the [EPA] Administrator," the 1977 amendments required the Administrator to create an "independent scientific review committee," now known as the Clean Air Scientific Advisory Committee (CASAC), with authority not only to review the scientific criteria developed by EPA but to "recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate..." (109(d)(2)) By inviting scientific advisors to make normative recommendations regarding what level is appropriate, this language deliberately confused the distinction between scientific expertise and policy judgment, codifying the input of hidden policy judgment and the is-ought fallacy into the policymaking process.<sup>50</sup>

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health risks disappear." Arrow, K.J. et. Al. National Ambient Air Quality Standards (NAAQS) Brief. Washington (DC): Joint Center, AEI-Brookings Joint Center for Regulatory Studies; 2000 July. Available at: [http://www.brookings.edu/~media/research/files/reports/2000/7/naaqs%20litan/07\\_naaqs\\_litan.pdf](http://www.brookings.edu/~media/research/files/reports/2000/7/naaqs%20litan/07_naaqs_litan.pdf) A former EPA science advisor observed regarding EPA's position that it "is not supposed to take cost into account in promulgating standards," "does any thinking person actually believe that they shouldn't, or don't?" (Dr. Joe Mauderly Comments on the NAAQS Review Process March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_0316-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_0316-06/$File/sabso-casac_memo_and_comments.pdf))

<sup>48</sup> Schoenbrod, D. "Politics and the Principle that Elected Legislators Should Make the Laws." *Harvard J. Law Public Policy* 2003, 26: 270, citing Clean Air Act Amendments of 1977: Hearings Before the Subcomm. on Env'tl. Pollution of the Senate Comm. on Env't and Public Works, 95th Cong. 8 (1977).

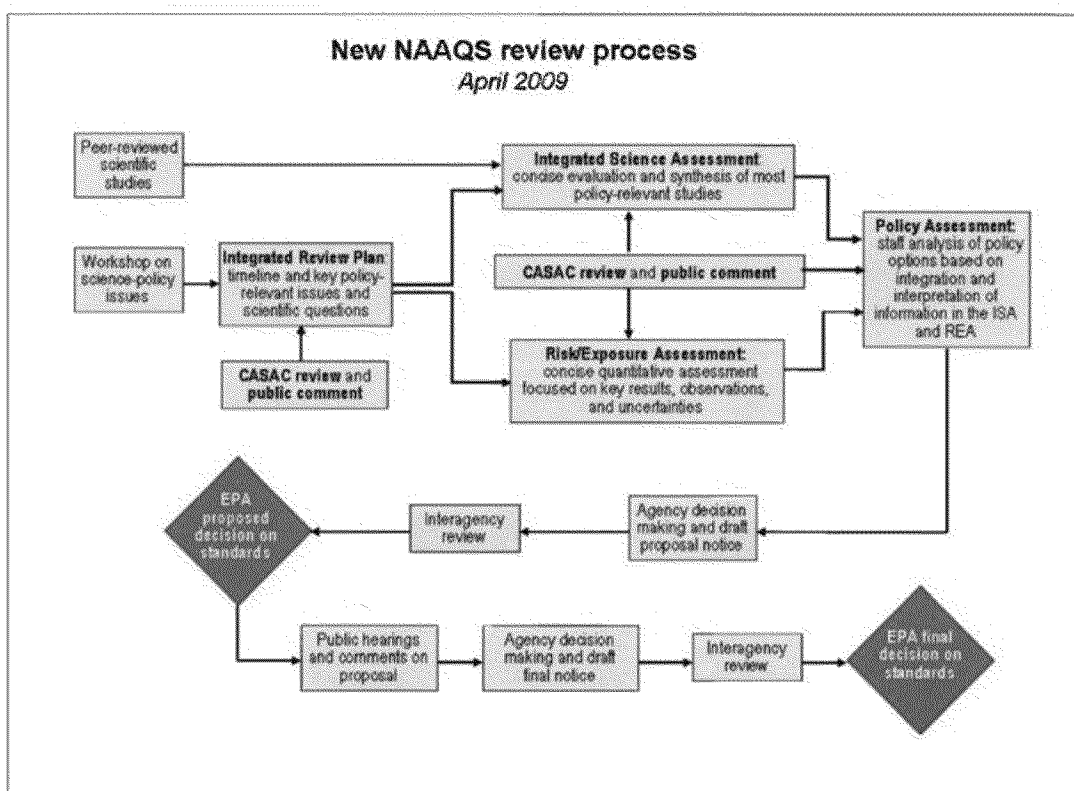
<sup>49</sup> Bipartisan Policy Center; 2009:4.

<sup>50</sup> The statutory role assigned CASAC makes it difficult to implement the Bipartisan Policy Center's recommendation that, "in general, scientific advisory panels should not be asked to recommend specific regulatory policies." Bipartisan Policy Center; 2009:17.

## Environmental Protection Agency

EPA follows a multi-step process when reviewing and setting NAAQS, as shown in Figure 2.<sup>51</sup> It begins by developing an Integrated Review Plan that identifies the science and policy issues that will be reviewed during the 5-year assessment. Next, EPA conducts extensive reviews of the available science in what is called an Integrated Science Assessment (ISA). Data on the criteria air pollutants are often extensive, with ISAs running to thousands of pages and including reviews of hundreds or thousands of studies. EPA staff use the results of the ISA to develop a risk and exposure assessment (REA) to evaluate potential risks associated with exposures expected at the existing standard and at alternative standards. To accomplish this, agency staff interpret various studies and data to generate a single concentration-response model to predict health effects at different levels of exposure. EPA's formulation and presentation of the studies and data necessarily involves judgments about which studies to consider and which to exclude, as well as assumptions about what models best fit the selected data and how to extrapolate between observed and predicted exposures.

Figure 2



<sup>51</sup> Craig, E. (EPA Acting Administrator for Air and Radiation). Letter to: Kadeli, L. (Acting Assistant Administrator for Research and Development). 2009 May 21. Process for Reviewing National Ambient Air Quality Standards. Available at: <http://www.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf>

Unfortunately, the many risk assessment policy judgments embedded in these models are not transparent. The findings of the ISA and REA depend heavily on how the staff decides to answer such nonscientific questions as what effects are considered “adverse,” how far to “err on the side of safety” when determining the appropriate shape of the exposure-response function, and whether observed associations are sufficient to assume causal effects, even in the absence of plausible biological evidence of causality. For example, EPA considers reversible, asymptomatic cellular changes and transient symptomatic effects (such as a cough) to be “adverse” which is clearly a matter of opinion, not something that can be determined solely on the basis of what “is.”

### **Treatment of uncertainty**

Perhaps the most pervasive hidden policy judgments regard the treatment of uncertainty. A recent report from the Institute of Medicine observed:

Uncertainty is inherent in the scientific information upon which health risk estimates are based. Uncertainties enter the health risk assessment process at every step and can be caused by the potential confounders in observational studies, by extrapolation from animal studies to human studies, by extrapolation from high to low dose exposures, by inter-individual variability, and by modeling the relationships between concentrations, human exposures, and human health responses and evaluating the effect of interventions or risk control options on public health risk.<sup>52</sup>

The uncertainties inherent in these assessments can be significant. For example, one key assumption that drives estimates of the effects of exposure to fine particles (PM<sub>2.5</sub>) is that “inhalation of fine particles is causally associated with premature death.”<sup>53</sup> EPA assumes a causal relationship based on epidemiological evidence of an association between PM concentrations and mortality, however, correlation does not imply causation (*cum hoc non propter hoc*), and EPA has not been able to identify a biological mechanism to explain the observed correlation. As Dominici, Greenstone and Sunstein observe, “associational approaches to inferring causal relations can be highly sensitive to the choice of the statistical model and set

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<sup>52</sup> Board on Population Health and Public Health Practice; Institute of Medicine. *Environmental Decisions in the Face of Uncertainty*, Committee on Decision Making Under Uncertainty, 2013. Available at: [http://www.nap.edu/catalog.php?record\\_id=12568](http://www.nap.edu/catalog.php?record_id=12568)

<sup>53</sup> Office of Information and Regulatory Affairs. *2012 Report to Congress On the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. Washington (DC): Office of Management and Budget, Executive Office of the President; 2013:19. Available at: [http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012\\_cb/2012\\_cost\\_benefit\\_report.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012_cb/2012_cost_benefit_report.pdf)

of available covariates that are used to adjust for confounding.”<sup>54</sup> Further, statistical experts have raised questions as to whether the correlation EPA claims is real, and present analysis that suggests EPA’s estimates of PM<sub>2.5</sub> mortalities are a product of model and data choices, rather than a real measured correlation.<sup>55</sup>

Another key assumption on which EPA’s estimates of adverse effects hinge is that the concentration-response function for fine particles is linear within the range of ambient concentrations under consideration. Both theory and data suggest that thresholds exist below which further reductions in exposure to PM<sub>2.5</sub> do not yield changes in mortality response, and that one should expect diminishing returns as exposures are reduced to lower and lower levels.<sup>56</sup> However, EPA assumes a linear concentration-response impact function that extends to concentrations down to zero.<sup>57</sup>

### Hidden biases

Based on its policy-related assumptions of a causal, linear, no-threshold relationship between PM<sub>2.5</sub> exposure and premature mortality, EPA quantifies a number of premature mortalities that will be avoided when concentrations of PM<sub>2.5</sub> decline as a result of regulation. If any of these assumptions are false (in other words, if no association exists, if the relationship is not causal, or if the concentration-response relationship is not linear at low doses), the effects of reducing PM<sub>2.5</sub> would be significantly less than EPA’s assessments estimate, including zero.

The assumptions of EPA’s scientists are not necessarily wrong, but each assumption in the face of uncertainty represents a decision based on policy considerations, not science. The extent to which a resulting standard should err on the side of safety reflects public values that the statute puts in the hands of the EPA Administrator and should be transparent to the public. Yet, these

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<sup>54</sup> Dominici, Francesca, Greenstone, Michael, & Sunstein, Cass R. “Particulate Matter Matters.” *Science* Vol 344. April 18, 2014.

<sup>55</sup> See, e.g., Cox L.A. “Reassessing the human health benefits from cleaner air.” 2012 May;32(5):816-29. Risk Analysis 2012, and Krstić, G. “A reanalysis of fine particulate matter air pollution versus life expectancy in the United States,” J Air Waste Manag Assoc. 2013 Feb;63(2):133-5. Cox’s statistical analysis suggests with a greater than 95% probability that no association exists, and that instead, EPA’s results are a product of its choice of models and selected data, rather than a real measured correlation. Krstić’s reanalysis shows that “the statistical significance of the correlation is lost after removing one of the metropolitan areas from the regression analysis, suggesting that the results may not be suitable for a meaningful and reliable inference.”

<sup>56</sup> See, for example Texas Commission on Environmental Quality, “PM<sub>2.5</sub> Standards may be set Lower than Scientifically Justifiable,” noting that “extrapolations [to current exposure levels] can be contrary to the basic principles of toxicology where the biological threshold (a level below which no effect is apparent) is a key concept.” Available at: [http://www.tceq.texas.gov/assets/public/comm\\_exec/pubs/pd/020/2013/OutlookMar-2013-x.pdf](http://www.tceq.texas.gov/assets/public/comm_exec/pubs/pd/020/2013/OutlookMar-2013-x.pdf)

<sup>57</sup> See final regulations governing PM<sub>2.5</sub> (Available at: <http://www.gpo.gov/fdsys/pkg/FR-2013-01-15/pdf/2012-30946.pdf>); Nitrogen dioxide (Available at: <http://www.gpo.gov/fdsys/pkg/FR-2010-02-09/html/2010-1990.htm>); and Ozone (Available at: <http://www.gpo.gov/fdsys/pkg/FR-2008-03-27/html/E8-5645.htm>)

uncertainties are not presented in the ranges of risks reported. Cox's review of EPA's ozone NAAQS proposed in December 2014 finds:

EPA has not quantified crucial model uncertainties. Therefore, confidence intervals calculated assuming that the models used are correct are misleadingly narrow and EPA has provided policy makers with no basis for confident predictions about how different changes in the ozone standard would probably affect public health.<sup>58</sup>

One former EPA science advisor called for "a more explicit characterization of uncertainty in estimates of causality and exposure-response relationships ... for both primary and secondary standards," noting:

At present, assessments of "uncertainty" are almost completely focused on the mathematical uncertainty of effects estimates (i.e., confidence intervals on measurements of exposures and effects). This is important of course, but I would like to see a more rigorous discussion of "certainty" in a broader sense. For example, how do the magnitudes of health effects of air pollution rank in comparison to other voluntary and involuntary health risks? Because air pollutants seldom, if ever, exert novel effects, what portion of the total public health effect is plausibly attributable to a pollutant (or to pollution)? What do we know about the relative benefits, and cost-benefit relationships, of different approaches to reducing health burdens that are exerted in part by air pollution? I care not that these issues might not fall within many folks' definition of "scientific information," or that EPA is not supposed to take cost into account in promulgating standards (does any thinking person actually believe that they shouldn't, or don't?). We delude ourselves and miss opportunities to inform policy makers and promote a rational public understanding of risk if we continue to view the "uncertainty" issue as solely one of statistical methodology and data quality, while advocating for the special importance of the particular effects ... by which we make our living.<sup>59</sup>

These uncertainties are further hidden from policy makers when, after the ISA and REA are completed, EPA staff prepares a Policy Assessment (formerly called the Staff Paper) that "bridges the gap" between the ISA and REA, and develops a set of policy options to present to the Administrator. The Policy Assessment "presents staff conclusions regarding the adequacy of

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<sup>58</sup> Cox, 2015

<sup>59</sup> Mauderly J. "Comments on the NAAQS Review Process," March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_0316-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_0316-06/$File/sabso-casac_memo_and_comments.pdf)



the current suite of standards as well as potential alternative standards for [the Administrator's] consideration."<sup>60</sup> This presentation of staff's judgment (informed by CASAC) regarding what is "requisite to protect public health" further obfuscates the line between science and policy judgment and virtually compels the staff to fall prey to the is-ought fallacy.<sup>61</sup> The Policy Assessment presents policy options framed with vague but portentous language, such as "the weight of the evidence" and "a consensus among scientific advisors." Uncertainty at lower levels of exposure is typically discussed vaguely and qualitatively to justify setting levels greater than zero.<sup>62</sup> As a result, the policy options presented by EPA staff, which clearly include nonscientific judgments, attempt to constrain the ultimate decision of the Administrator, who is the accountable decision maker under the Clean Air Act. The staff recommendations, shrouded in scientific language, create a science charade.

One would have difficulty discerning the large impact of nonscientific decisions just by reading the recommendations. For example, the Policy Assessment EPA staff prepared for the fine particle standards set in December 2012 states:

Taking into account both evidence-based and risk-based considerations, staff concludes that consideration should be given to revising the current annual PM<sub>2.5</sub> standard level of 15 µg/m<sup>3</sup> to a level within the range of 13 to 11 µg/m<sup>3</sup>. Staff further concludes that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 µg/m<sup>3</sup>.<sup>63</sup>

### **Public communication**

Documents prepared to support executive requirements for economic analysis and to communicate with the public also suffer from a science charade. EPA staff prepares a Regulatory Impact Analysis (RIA), and publicly releases it concurrently with proposed and final

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<sup>60</sup> United States Environmental Protection Agency, Office of Air and Radiation. Policy Assessment for the Review of Particulate Matter National Ambient Air Quality Standards, Second External Review Draft. Washington (DC): United States Environmental Protection Agency; 2010 June. Available at:

<http://www.epa.gov/ttnnaqs/standards/pm/data/20100630seconddraftmpa.pdf>

<sup>61</sup> A committee charged with identifying PM research needs did not look at the adequacy of scientific basis for a NAAQS standard "because the process of setting such standards also involves legal requirements and policy choices that the present committee was neither charged nor constituted to address." Committee on Research Priorities for Airborne Particulate Matter, National Research Council. Research Priorities for Airborne Particulate Matter. Washington (DC): National Academic Press; 1998.

<sup>62</sup> For example, the December 2014 ozone proposal argues that "setting a standard below 0.065 ppm, down to 0.060 ppm, would inappropriately place very little weight on the uncertainties in the health effects evidence and exposure/risk information." 79 FR 65236

<sup>63</sup> Office of Air and Planning. Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards. United States Environmental Protection Agency; 2011. Available at: <http://www.epa.gov/ttnnaqs/standards/pm/data/20110419pmpafinal.pdf>

determinations. RIAs are required by executive order to “assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.”<sup>64</sup> This document is not depicted on the decision diagram (shown above), and EPA is explicit that “the RIA is done for informational purposes only, and the final decisions on the NAAQS are not in any way based on consideration of the information or analyses in the RIA.” The results of the RIA feature prominently in EPA press releases, however. For the December 2012 PM<sub>2.5</sub> NAAQS, EPA announced that meeting the Administrator’s selected standard of 12.0 µg/m<sup>3</sup> standard would avoid between 460 and 1,000 premature deaths per year. However, the RIA also indicated that further tightening—going from a standard of 12 µg/m<sup>3</sup> to 11 µg/m<sup>3</sup>—would yield additional life savings of 1,040 to 2,300 mortalities per year.

Given that these two data points suggest the incremental life savings associated with a reduction from 12 µg/m<sup>3</sup> to 11 µg/m<sup>3</sup> are greater than those associated with a reduction from 13 µg/m<sup>3</sup> to 12 µg/m<sup>3</sup>, it is curious that the Policy Assessment did not recommend, or at least examine, standards below 11 µg/m<sup>3</sup>. Neither the Policy Assessment nor RIA explains this, nor the Administrator’s decision to set a standard of 12 µg/m<sup>3</sup>, which these documents suggest leave between 580 and 1,300 lives unprotected.

Instead the RIA justifies the standards as follows:

This action provides increased protection for children, older adults, persons with pre-existing heart and lung disease, and other at-risk populations against an array of PM<sub>2.5</sub>-related adverse health effects that include premature mortality, increased hospital admissions and emergency department visits, and development of chronic respiratory disease. ... The revised suite of PM<sub>2.5</sub> standards also reflects consideration of a quantitative risk assessment that estimates public health risks likely to remain upon just meeting the current and various alternative standards. Based on this information, the Administrator concludes that the current primary PM<sub>2.5</sub> standards are not requisite to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that these revisions are warranted to provide the appropriate degree of increased public health protection.

As a former senior EPA air office official observed about the 1997 standard:

Nuance and uncertainty were also lacking in EPA’s public communications after proposal. The agency’s sound bite was that the science demanded the revisions. Although it was true that EPA’s assessment of the science found a need to tighten

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<sup>64</sup> Executive Order 12866, Section 1(a). 1993

the standards, the *particular* standards proposed were obviously not wholly determined by science.<sup>65</sup>

The statutory language forces EPA staff to present vague justifications that are careful not to express considerations of economic tradeoffs. Yet, because there is no threshold below which models do not predict health effects, short of eliminating these criteria pollutants altogether, science alone cannot identify what standard along the modeled linear no-threshold dose-response function would be “requisite to protect public health.” And yet, all involved regularly participate in a science charade in which EPA sets standards at non-zero levels and justifies the decision based solely on arguments that are characterized as strictly scientific.

### Clean Air Scientific Advisory Committee

The Clean Air Scientific Advisory Committee is a seven-member committee the Clean Air Act established “to provide advice and recommendations to EPA.”<sup>66</sup> Members are chosen on the basis of their scientific expertise, generally serve for two consecutive three-year terms, and meet 12 to 15 times a year. Their expertise is often supplemented by panels of 20 or more experts on the health and environmental effects of the specific pollutants that are under review. As Figure 2 shows, these CASAC panels are involved at all stages of the NAAQS development process.

As recent reports from the Keystone Center and BPC have observed, scientific advisory panels can provide valuable input to agency decision making. However, they caution that “in general, scientific advisory panels should not be asked to recommend specific regulatory policies”<sup>67</sup> or “to answer questions that go beyond matters of scientific judgment.”<sup>68</sup> As noted above, the Clean Air Act authorizes CASAC to recommend “new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate.” Similar to the problem discussed above with respect to EPA staff, this allows CASAC to make hidden policy judgments couched in scientific terms and attempt to influence the Administrator’s final policy decision. Note that the Act does not go so far as to require CASAC’s *approval* of the Administrator’s policy choice, and a Congressional Research Service (CRS) review of the history of CASAC observed that, until recently, committees eschewed the role of approver:

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<sup>65</sup> Bachmann, 2007: 687

<sup>66</sup> See EPA Science Advisory Board. United States Environmental Protection Agency Charter. Environmental Available at: <http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/currentcharter?OpenDocument>

<sup>67</sup> Bipartisan Policy Center, 2009: 5.

<sup>68</sup> The Keystone Center. Research Integrity Roundtable. *Improving the Use of Science in Regulatory Decision Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews*. Washington (DC): The Keystone Center, 2012: 8. Available at: [https://www.keystone.org/images/keystone-center/spp documents/Health/Research%20Integrity%20Roundtable%20Report.pdf](https://www.keystone.org/images/keystone-center/spp/documents/Health/Research%20Integrity%20Roundtable%20Report.pdf)

CASAC panels have a nearly 30-year history of working quietly in the background, advising the agency's staff on NAAQS reviews, and issuing what were called "closure letters" on the agency documents that summarize the science and the policy options behind the NAAQS. Closure letters have been used by CASAC panels to indicate a consensus that the agency staff's work provides an adequate scientific basis for regulatory decisions. The science and policy documents, written by EPA staff, generally have gone through several iterations before the scientists were satisfied, but, with the issuance of a closure letter, CASAC has in past years removed itself from the process, leaving the formal proposal and final choice of standards to the Administrator.<sup>69</sup>

This CASAC behavior of detaching itself from the final policy process was consistent with Weinberg's recommendation in his landmark paper on "trans-science," in which he observed:

Though the scientist cannot provide definite answers to trans-scientific questions any more than can the lawyer, the politician or a member of the lay public, he does have one crucially important role: to make clear where science ends and trans-science begins.<sup>70</sup>

### **Recent CASAC panels take forceful policy positions**

Going beyond the more subtle hidden policy judgment asked of CASAC in the statute, recent Committees have been more aggressive at advocating their public policy decisions and openly criticized administrators who deviate from their recommendations. For instance, in 2006, after the EPA Administrator issued standards outside the range recommended by CASAC, the committee took the unprecedented action of writing to the Administrator that the standard "does not provide an 'adequate margin of safety... requisite to protect the public health' (as required by the Clean Air Act)..."<sup>71</sup>

In an excellent example of a science charade, in 2008, CASAC's ozone review panel stated in a letter to EPA that its members:

*do not endorse the new primary ozone standard as being sufficiently protective of public health.* The CASAC — as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards

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<sup>69</sup> McCarthy, James. E. "Air Quality Standards and Sound Science: What Role for CASAC?" CRS Report RL33807, January 19, 2007:2. Available at: <http://www.policyarchive.org/handle/10207/bitstreams/3076.pdf>

<sup>70</sup> Weinberg, Alvin M. 1972.

<sup>71</sup> Letter of Rogene Henderson et al. (of the Clean Air Scientific Advisory Committee) Letter to: to Hon. Stephen L. Johnson EPA Administrator) regarding the PM NAAQS, Sep 2006. Available at: <http://www.epa.gov/sab/pdf/casac-ltr-06-003.pdf>. Italics in original.

— *unanimously recommended* decreasing the primary standard to within the range of 0.060–0.070 ppm. It is the Committee’s consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations.<sup>72</sup> (emphasis in original)

The CRS report observes that CASAC’s recent advocacy deviates from its past practice, when it refrained from objecting to policy decisions that differed from its recommendations. It points to two examples where EPA administrators took no action to revise standards, despite staff and CASAC recommendations that the standards be tightened: in 1990, with regard to the lead NAAQS, and in 1996, with regard to the sulfur dioxide NAAQS. CASAC did not object in either case.<sup>73</sup> In a more recent case, CASAC did not publicly object to Administrator Lisa Jackson’s decision not to revise the primary standard for coarse particles (PM<sub>10</sub>) in 2012, despite its conclusion that “it is clear that the current PM<sub>10</sub> standard is not adequate to protect the public health,”<sup>74</sup> and recommendation “that the primary standard for PM<sub>10</sub> should be revised downwards.”<sup>75</sup>

### **Distinction between science and policy blurred**

The more activist stance of recent committees clearly crosses the line between science and policy. In response to an EPA workgroup effort to improve the NAAQS process, several former CASAC members expressed concerns about CASAC’s ability to distinguish between science and policy recommendations.

Former CASAC member, Dr. Ellis Cowling, cautioned:

The responsibility of scientists, engineers, and policy analysts is to understand and clearly communicate the scientific facts and uncertainties and to describe expected outcomes objectively. Deciding what to do involves questions of

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<sup>72</sup> Letter of Rogene Henderson et al. of the Clean Air Scientific Advisory Committee to Hon. Stephen L. Johnson, EPA Administrator, April 7, 2008, Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4AF8764324331288852574250069E494/\\$File/EPA-CASAC-08-009-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/4AF8764324331288852574250069E494/$File/EPA-CASAC-08-009-unsigned.pdf). This may be one of the best examples of a nonscientific recommendation being couched as being based purely “scientific opinion.”

<sup>73</sup> McCarthy, James. E. 2007:9.

<sup>74</sup> Dr. Jonathan M. Samet et al. letter of the Clean Air Scientific Advisory Committee to Hon. Lisa Jackson, EPA Administrator. May 17, 2010. EPA-CASAC-10-011

<sup>75</sup> Dr. Jonathan M. Samet et al. letter of the Clean Air Scientific Advisory Committee to Hon. Lisa Jackson, EPA Administrator. September 10, 2010. EPA-CASAC-10-015

societal values where scientists, engineers, and policy analysts have no special authority.<sup>76</sup>

Former chairman, Bernard D. Goldstein, M.D., reflected on his experience:

I found a sense among several CASAC members that the CASAC is responsible for approving the proposed standards rather than giving advice and recommendations. The Agency should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice. The line between science and policy is not always apparent, and this difference should be made clear in the charge questions given to CASAC.<sup>77</sup>

Dr. George T. Wolff made a similar point, observing:

The selection of a particular level for a standard is a policy judgment. CASAC's job is to insure that the range, form and averaging time recommended in the Staff Paper have a scientific basis. In questioning the recommendations in the January 17, 2006 NPRM, CASAC has clearly overstepped their boundaries and ventured into the policy arena.<sup>78</sup>

Former CASAC chairman, Dr. Joe Mauderly, observed:

Neither scientists nor policy makers want to draw the line [between science and policy], or to define it or admit to it. CASAC meetings are rife with discussions about how its pronouncements will affect policy, and scientist advocates (on CASAC and its panels, as well as others) game the system to achieve their ideological policy goals. When EPA proposes or promulgates standards, it is reluctant to state clearly how science and policy enter into the decision—it wants to portray that all is based on science. These behaviors are absolutely understandable—most scientists are convinced that they know what's best for the

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<sup>76</sup> Cowling, Ellis. "Comments on the NAAQS Review Process," March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_03-16-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf)

<sup>77</sup> Goldstein, Bernard, M.D. "Comments on the NAAQS Review Process." March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_03-16-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf)

<sup>78</sup> Wolff, George T. "Comments on the NAAQS Review Process," March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_03-16-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf)

country, and EPA Administrators don't want to admit to any motive other than the "best science."<sup>79</sup>

The bald consideration of nonscientific factors by CASAC in making its recommendations is illustrated in the committee's deliberations on the 2007 lead NAAQS. Members objected to the standard the Administrator was considering because "it wouldn't create any pressure on any person producing lead in the environment today from reducing because it doesn't leave any more exceedances than the current standard."<sup>80</sup> They presented various non-science arguments in support of their preferred, more stringent, policy option, including the "need to regulate it at a level that causes public attention to come to the problem," and that "causes the most severe polluters to have to put in additional controls..."<sup>81</sup>

The Committee discussions appear to suffer from the symptoms identified in the organizational behavior literature regarding group behavior, including

close-mindedness, involving a collective effort "to rationalize" so as to discount warnings or information that might lead to reconsideration, and stereotyped views of enemies, as too evil to warrant efforts at negotiation or "too weak and stupid to counter" the group's... choices.<sup>82</sup>

Transcripts of CASAC's 2007 meetings on the lead NAAQS decisions, for example, reveal that its members had few real disagreements with each other or with EPA staff. This means the committee likely lacked the value of independent analysis and challenge that is so essential to the scientific method. The discussions appear to exhibit the "asymmetrical trust" symptomatic of insular group dynamics that perpetuates an "us vs. them" mindset.<sup>83</sup> While committee members treat each other and EPA staff, with whom they often have a close working relationship, with respect, their comments reflect a "stereotyped view of enemies," including policy officials, other agency staff, and the public.<sup>84</sup> For example, committee members objected strongly to providing the broader public an opportunity to comment on issues not preapproved by the committee, and members expressed the view that anyone not part of the committee likely had a conflict of interest.<sup>85</sup>

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<sup>79</sup> Mauderly, J. "Comments on the NAAQS Review Process." March 3, 2006. Available at: [http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_03-16-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_03-16-06/$File/sabso-casac_memo_and_comments.pdf)

<sup>80</sup> US EPA CASAC Lead Review Panel Public Advisory Meeting 2/7/07 CCR # 14610-13 page 15

<sup>81</sup> US EPA CASAC Lead Review Panel Public Advisory Meeting 2/7/07 CCR # 14610-13 pages 15-16

<sup>82</sup> Sunstein, Cass. *Going to Extremes: How Like Minds Unite and Divide*. New York: Oxford University; 2009:86.

<sup>83</sup> Sunstein, 2009.

<sup>84</sup> US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 145

<sup>85</sup> US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 33. Members objected to seeking public comment on issues because that put commenters "on an equal basis with the CASAC," and constituted "taking a group that has a clear conflict of interest and treating them as though they are equal to CASAC."

## **CASAC panels may lack diversity**

Former CASAC chair George Wolff has raised concerns that EPA's selection of panel members exacerbates this problem. He noted several differences between the panel reviewing the 1997 fine particle NAAQS and the 2006 standard, including a change in the composition of the panels:

In the 1994-96 review, there were a number of Panel members who were skeptical that the epidemiology studies demonstrated cause and effect including one biostatistician and one epidemiologist who were not authors of the studies that found statistical links between PM and health endpoints. As a result, the Panel expressed "a diversity of opinion."

When the new Panel was formed, most of the Panel members who supported a causal role in 1996 were invited back to be on the new panel. Most of the skeptics were not. Instead they were replaced by individuals that, on the balance, were more supportive of the Agency's position. In fact, by the time the Panel concluded the review, seven out of 22 members had been authors of papers that purport causality. No epidemiologist or statistician who questioned causality was a member of the Panel. This lack of balance on the Panel predetermined the outcome of the review.<sup>86</sup>

Former CASAC chair Roger McClellan expressed concern that CASAC panel "membership has been excessively dominated by scientists that to a large extent have developed the scientific information contained in the documents [they are charged with reviewing]," noting that "in some cases, the individuals have already offered opinions as to how the science should be used to set...a more stringent standard based on their science."<sup>87</sup> According to a Congressional investigation, 16 of the 20 members of the CASAC panel charged with reviewing the science in support of the 2015 ozone NAAQS had conducted studies they were supposed to evaluate, and 14 of the 20 members had been principal or co-investigators for EPA grants totaling more than \$120 million.<sup>88</sup>

## **CASAC's treatment of uncertainty**

The unabashed crossing of the line between science and policy is also evident in the treatment of uncertainty and risk communication. Although the members of CASAC recognize the

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<sup>86</sup> Wolff, 2006.

<sup>87</sup> Committee on Science, Space, and Technology hearing, "Quality Science for Quality Air," 112<sup>th</sup> Cong., 1<sup>st</sup> sess, October 4, 2011. <http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/html/CHRG-112hhrg70587.htm>

<sup>88</sup> Lamar Smith, Chairman Committee on Science, Space, and Technology letter to EPA Administrator letter to Gina McCarthy. March 19, 2014. <http://science.house.gov/sites/republicans.science.house.gov/files/documents/03-19-2014%20Smith%20to%20Administrator%20McCarthy.pdf>



uncertainty inherent in supporting analyses, the drive for a narrow range of policy options may limit their willingness to quantify the full uncertainty range or to explore the quantitative implications of alternative science policy choices. For example, the 2007 lead NAAQS transcript reveals that CASAC members were initially critical of an EPA method for measuring health effects on the grounds that it was oversimplified and didn't rely on current data and modeling techniques. When EPA staff pointed out that this simplified method would more likely lead policy makers to a level already preferred by CASAC, compared to the more sophisticated method, CASAC members dropped their objections.<sup>89</sup>

CASAC's position on how to manage uncertainty is another example of a hidden policy decision. The strongly-worded letter objecting to the Administrator's policy decision on the 2006 PM<sub>2.5</sub> NAAQS, states that, "while there is uncertainty associated with the risk assessment for the PM<sub>2.5</sub> standard, this very uncertainty suggests a need for a prudent approach to providing an adequate margin of safety."<sup>90</sup>

Yet, this assertion that uncertainty demands a "prudent" policy decision stands in contrast to the statement of former chairman, Bernard Goldstein, who told EPA:

How one deals with the uncertainties is a policy issue. One can say that a lot of uncertainty suggests being more conservative to be sure we are "safe." Another policy might be that a large amount of uncertainties means that we cannot select appropriate levels until we have more information. In any case, the amount of uncertainty should be fully addressed and central estimates should be given as well as the upper and lower confidence limits. Again, the policy decisions made should be explicit and clearly stated in public.<sup>91</sup>

As this discussion has shown, CASAC members' views of their role has evolved over time to be increasingly involved in the policy decision as to the level at which the standard should be set, yet still present such a recommendation as "science." This may be due, in part, to the individuals EPA staff select to serve on the committee and panels,<sup>92</sup> and the charge EPA gives them.<sup>93</sup> As discussed further below, members' views constrain policy officials and the courts, and influence public opinion. When differences of opinion about policies are cast as scientific disagreements, accusations of politicized science arise. However, as the BPC noted, "some disputes over the 'politicization' of science actually arise over differences about policy choices that science can

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<sup>89</sup> US EPA PUBLIC MEETING 12/12/07 CCR# 15740-1 Page 67

<sup>90</sup> CASAC letter to EPA Administrator Johnson, September 29, 2006. EPA-CASAC-LTR-06-003

<sup>91</sup> Goldstein, 2006.

<sup>92</sup> Wolff, 2006.

<sup>93</sup> As former CASAC chair Bernard D. Goldstein, M.D. observed, EPA "should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice." Comments on the NAAQS Review Process March 3, 2006.

inform, but not determine.”<sup>94</sup> The role of CASAC in setting NAAQS illustrates processes that both perpetuate hidden policy judgments and science charades, inviting use of the is-ought fallacy.

## Policy Officials

Under the Clean Air Act, it is the EPA Administrator (and thus the president at whose pleasure she serves) who is ultimately responsible for issuing primary NAAQS, “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”<sup>95</sup> Similarly the Act requires the Administrator to set secondary NAAQS at a level which, in her judgment, “is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air.”<sup>96</sup> Though EPA staff prepares a regulatory impact analysis, including an assessment of the likely costs and benefits of achieving different standards, the Administrator does not consider it, and staff does not present it to her.<sup>97</sup>

As discussed above, in choosing the level of the standard, the Administrator faces pressure from EPA staff and CASAC members. In addition, outside groups, including state and local governments (which are responsible for implementing and achieving the standard), potentially regulated parties, non-governmental organizations (NGOs), and Congress attempt to influence the Administrator’s decision. Also, other Administration officials (who often are responsible for implementing competing policy goals and may also be hearing from constituencies outside the government) may seek to sway the Administrator’s determination.

The Administrator deviates from the recommendations of the Policy Assessment and CASAC at her peril.<sup>98</sup> If she makes a decision outside of the staff and CASAC recommendations presented to her, the Administrator runs the risk that NGOs will file suit to overturn her decision (possibly with support from EPA staff, who may even work with the Justice Department to make sure that the Administrator loses the lawsuit).<sup>99</sup> Particularly in the context of a science charade, public disagreement also puts policy officials at a public relations disadvantage, when exercising policy

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<sup>94</sup> Bipartisan Policy Center, 2009.

<sup>95</sup> 42 USC § 7409(b)(1)

<sup>96</sup> 42 USC § 7409(b)(2)

<sup>97</sup> According to the Regulatory Impact Analysis conducted in association with the final particulate matter standard set in December 2012, “[i]n NAAQS rulemaking, the RIA is done for informational purposes only, and the final decisions on the NAAQS in this rulemaking are not in any way based on consideration of the information or analyses in the RIA.”

<sup>98</sup> CASAC letter to EPA Administrator Johnson, September 29, 2006. EPA-CASAC-LTR-06-003

<sup>99</sup> See, for instance, Kelli Hayes, “Sue and Settle: Forcing Government Regulation Through Litigation,” *University of Dayton Law Review*, 40:105 (2015)

[https://www.udayton.edu/law/resources/documents/law\\_review/vol40\\_no1/sue\\_and\\_settle.pdf](https://www.udayton.edu/law/resources/documents/law_review/vol40_no1/sue_and_settle.pdf)

judgment is characterized as going against science.<sup>100</sup> For instance, both Presidents Obama and Bush were accused of politicizing science when they chose not to regulate ozone at the levels recommended by CASAC and the staff Policy Assessment.<sup>101</sup> Particularly when it comes to environmental and health experts, “it is difficult for political executives to reject their recommendations.”<sup>102</sup>

It is important to point out that hidden policy judgments by scientists not only discourage policy makers from setting standards higher than those recommended by staff, but lower as well. At one point in the development of the 2008 lead NAAQS, consideration was given to seeking public comment on whether zero was appropriate as the lower end of the range at which to set the standard. Given the lack of a threshold in health effects, and CASAC’s unanimous and vocal opinion that lead remained a very serious public health risk, some policy officials questioned the justification for setting any standard above zero.<sup>103</sup> Available data and modeling made it difficult for the Administrator to conclude that a lead ambient air quality standard of 0.15 ug/m<sup>3</sup> was “requisite” to protect public health with an “adequate margin of safety,” but 0.5 ug/m<sup>3</sup> or 0 ug/m<sup>3</sup> was not. EPA Air Office staff (perhaps correctly) perceived this as an effort to expose the inherent contradictions in the NAAQS provisions of the Clean Air Act, and they strongly objected to it. In the face of staff opposition, Administrator Johnson chose not to present the wider range for public comment. It is much safer, from a political and staff management viewpoint, for Administrators to stay inside the policy box EPA staff and CASAC have created for them.<sup>104</sup>

Sometimes the influence of the staff and CASAC is so strong that the decision requires an explicit and public policy judgment to be made above the Administrator and carefully explained to the public. In 2008, during the interagency review of EPA’s ozone NAAQS, disagreement over the form of the secondary “welfare” standard was so contentious that President Bush ultimately had to step in to resolve it.<sup>105</sup> Deliberations within the executive are generally not public, but in this case the Administrator was very reluctant to select a form different from that

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<sup>100</sup> See, for example, Union of Concerned Scientists blog, “EPA Air Pollution Decision Threatens Public Health: Science Disregarded, Misrepresented on Particulate Matter Standard.”  
[http://www.ucsusa.org/scientific\\_integrity/abuses\\_of\\_science/epa-air-pollution-decision.html](http://www.ucsusa.org/scientific_integrity/abuses_of_science/epa-air-pollution-decision.html)

<sup>101</sup> See for example: [http://switchboard.nrdc.org/blogs/jwalke/the\\_president\\_sabotages\\_clean.html](http://switchboard.nrdc.org/blogs/jwalke/the_president_sabotages_clean.html)

<sup>102</sup> R. Shep Melnick, *Regulation and the Courts: The Case of the Clean Air Act*, Brookings Institution: Washington DC (1983), p. 295.

<sup>103</sup> Authors’ personal experiences in NAAQS discussions as administrator of OIRA and deputy administrator of EPA.

<sup>104</sup> Mauderly, 2006, noting “most scientists are convinced that they know what’s best for the country, and EPA Administrators don’t want to admit to any motive other than the ‘best science.’”

<sup>105</sup> In the rarely-used section 7 of E.O. 12866, “conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President.”

recommended by staff.<sup>106</sup> Out of respect for his concern, correspondence between the OIRA Administrator and Deputy Administrator of EPA explaining their respective positions was shared publicly on the agencies' websites,<sup>107</sup> and the final preamble to the rule acknowledged the disagreement and that it was the President who concluded what the appropriate form of the standard should be.<sup>108</sup>

## States

States have a great interest in the level of the NAAQS. Under the Act, EPA establishes the allowable concentration of each pollutant in the ambient air, but the burden falls on states to develop implementation plans that achieve those levels. Under the statute, areas not in attainment with the standard face restrictions on economic growth.<sup>109</sup> If a state fails to develop a plan that meets with EPA's approval, the agency may impose a more restrictive (and possibly punitive) Federal Implementation Plan; the federal government can also withhold federal highway funding from states chronically out of attainment, although it has not yet done so. By imposing the obligation of NAAQS attainment on the states, EPA effectively commandeers, not only the considerable state resources that are needed to carry out the program, but also the much broader array of police powers that states enjoy. State Implementation Plans may include land use controls and other regulatory options that are not available to EPA under the Constitution, let alone the Clean Air Act.

And yet, it may not be enough. Since the EPA Administrator cannot consider the feasibility of achieving a standard when revising it, the NAAQS for several criteria pollutants have put large geographic areas out of attainment, particularly the more densely populated urban areas of the Northeast and Pacific coast, with no realistic options for successful implementation. Los Angeles and surrounding areas, for example, cannot comply with the 0.08 ppm ozone NAAQS set in the 1990s, to say nothing of the tighter 0.075 ppm standards established in 2008 or the even tighter 0.070 ppm standard<sup>110</sup> set in 2015.<sup>111</sup>

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<sup>106</sup> Authors' personal experiences in NAAQS discussions as administrator of OIRA and deputy administrator of EPA.

<sup>107</sup> See memo from Susan Dudley to Steve Johnson on OIRA's RegInfo site:

[http://www.reginfo.gov/public/postreview/Steve\\_Johnson\\_Letter\\_on\\_NAAQs\\_final\\_3-13-08\\_2.pdf](http://www.reginfo.gov/public/postreview/Steve_Johnson_Letter_on_NAAQs_final_3-13-08_2.pdf).

<sup>108</sup> Environmental Protection Agency. "National Ambient Air Quality Standards for Ozone." 73 FR 16497.

<http://www.gpo.gov/fdsys/pkg/FR2008-03-27/pdf/E8-5645.pdf>

<sup>109</sup> Greenstone, M., List J.A., Syverson, C. "The Effects of Environmental Regulation on the Competitiveness of U.S. Manufacturing." MIT Center for Energy and Environmental Policy Research working paper. CEEPR WP 2012-013; 2012.

<sup>110</sup> <https://www.gpo.gov/fdsys/pkg/FR-2015-10-26/pdf/2015-26594.pdf>

<sup>111</sup> Environmental Protection Agency.

<http://www.epa.gov/groundlevelozone/designations/2008standards/final/finalmap.htm>

Ironically, the states unable to comply with current standards are typically more supportive of stricter standards than the states that are in attainment. Eight of the fifteen states that filed comments that supported tightening the ozone NAAQS set in 2008 were unable to meet the existing standard, and would certainly not be able to comply with a tighter standard. Not only do non-attainment states file comments on proposed standards, but several recently threatened to sue EPA for failure to issue more stringent standards.<sup>112</sup> In contrast, of the six states that filed comments that opposed tightening the ozone NAAQS, four were in “maintenance,” meaning they had recently achieved compliance.

This may not be as surprising as it initially appears. Nonattainment areas have trouble attracting new businesses, and their citizens suffer (or move) when potential job-creating industries settle in other states. Greenstone et al. have quantified the economic losses associated with nonattainment status, finding that

total factor productivity (TFP) among plants that emit the targeted pollutants... declines by 4.8 percent for polluting plants in nonattainment counties. This corresponds to an annual economic cost from the regulation of manufacturing plants of roughly \$21 billion in 2010 dollars. This translates into a loss of more than \$450 billion over the studied period [1972 to 1993].<sup>113</sup>

From the perspective of nonattainment areas, strict standards that throw areas in other states out of attainment “level the playing field.” Areas that are already out of attainment have little to lose from stricter standards, but they gain relative to competing states which will have nonattainment conditions imposed on them. Even though parts of California have been unable to meet the ozone NAAQS set in the 1990s, California legislators were the most vocal proponents of yet more stringent ozone standards in 2008, accusing EPA of considering factors other than public health in setting the NAAQS.<sup>114</sup>

Absent a federal mandate, states would be expected to compete with each other in providing environmental quality, as well as economic prosperity. State officials know that voters demand environmental quality, and they also know that it affects property values—which in turn affect the state tax base, including funding for local governments and school districts. The overlay of mandatory federal NAAQS, however, suppresses and redirects this virtuous interstate competition. EPA’s oversight of NAAQS attainment acts in much the same way that economic regulation affects an otherwise competitive industry.<sup>115</sup> Instead of competing in the provision of air quality, states may be motivated to direct their energies to lobbying the regulator, seeking

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<sup>112</sup> [http://www.epa.gov/ttn/naaqs/standards/ozone/data/ENV\\_DEFENSE-650358-v1-Ozone\\_NAAQS\\_decision.pdf](http://www.epa.gov/ttn/naaqs/standards/ozone/data/ENV_DEFENSE-650358-v1-Ozone_NAAQS_decision.pdf)

<sup>113</sup> Greenstone & Syverson, 2012.

<sup>114</sup> <http://online.wsj.com/article/SB121115921730002453.html>

<sup>115</sup> See discussion regarding “presumption against economic regulation” in OMB Circular A-4, “Regulatory Analysis.” Available at: <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>

lenient treatment for themselves while advocating economically stifling restrictions on their competitors. State politicians present themselves to the voters as high-minded, if ineffectual, champions of environmental quality.<sup>116</sup>

## Courts

As noted earlier, the United States Supreme Court confirmed EPA's statutory interpretation that it cannot consider costs when setting NAAQS.<sup>117</sup> EPA notes, however, that the Act "does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentration levels, *see Lead Industries Ass'n v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety."<sup>118</sup>

States supporting more stringent standards are joined by NGOs, such as the American Lung Association and the Natural Resources Defense Council, in seeking a remand of EPA standards on the grounds that they are not adequately protective according to statutory criteria.<sup>119</sup> States supporting less stringent standards sue EPA seeking to have NAAQS vacated because the Agency did not establish that the standards are requisite to protect health and welfare under the meaning of the Act. These states are supported by industry litigants (such as the U.S. Chamber of Commerce, the Utility Air Regulatory Group, and the National Association of Home Builders).<sup>120</sup> Given the statutory construction, none of the litigants openly express policy arguments for preferring one standard over another, but rather they couch their legal arguments in terms of science—highlighting differences between CASAC's recommended levels and the Administrator's choice, and debating what science is needed to determine what levels are "requisite" to protect public health and welfare, and what qualifies as an "adequate margin of safety."<sup>121</sup>

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<sup>116</sup> This behavior is consistent with economic theory regarding regulation, particularly the colorfully named "bootlegger and Baptist" theory. Smith, Adam, Yandle, Bruce. *Bootleggers and Baptists: How Economic Forces and Moral Persuasion Interact to Shape Regulatory Politics*. Cato Institute. 2014.

<sup>117</sup> *Whitman v. American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001)

<sup>118</sup> National Ambient Air Quality Standards for Particulate Matter; Final Rule. January 15, 2013. Available at: <http://www.gpo.gov/fdsys/pkg/FR2013-01-15/pdf/2012-30946.pdf>

<sup>119</sup> See, for example, OPENING BRIEF OF STATE PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369352 Filed: 04/17/2012, arguing that EPA's 2008 ozone NAAQS be remanded "on grounds that the primary NAAQS does not protect public health with an adequate margin of safety and the secondary NAAQS does not protect public welfare, as required under the Act"; and PROOF BRIEF FOR ENVIRONMENTAL PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369354 Filed: 04/17/2012.

<sup>120</sup> See, for example, JOINT OPENING BRIEF OF PETITIONER STATE OF MISSISSIPPI AND INDUSTRY PETITIONERS in STATE OF MISSISSIPPI, et al v. EPA. USCA Case #08-1204 Document #1369355 Filed: 04/17/2012.

<sup>121</sup> Bachmann notes that "in the pre-proposal period, [interest] groups tried to influence the scientific basis for EPA's decisions," while "during the post-proposal period, the emphasis shifted to providing Congress, local elected

Lower courts also help enforce the Act's requirement for reviews of the standards every five years. In response to litigation over missed statutory deadlines, the government will enter into consent decrees that impose judicial deadlines for issuing standards.<sup>122</sup> Particularly given the steps involved in preparing the regulatory record in NAAQS proceedings, these deadlines constrain the opportunity for meaningful public consultation and interagency review.<sup>123</sup> EPA often submits draft regulations to OIRA for interagency review just days before such deadlines.<sup>124</sup>

Even as the courts drive the NAAQS process forward and enforce the Clean Air Act's procedural requirements, they avoid questioning anything in the administrative record that is characterized as science. This understandable deference to agency fact-finding has a curious result: it tends to limit the EPA Administrator's ability to exercise the policy discretion that the Congress has entrusted to her. If she makes a policy decision that conflicts with the policy preferences of EPA staff or science advisors, there will be a conflict in the administrative record, falsely framed as a policy choice inconsistent with the "science." Judges find it easy to vacate administrative decisions in such circumstances. Whatever doubts she may have about the merits of the options placed before her, the safest thing for the Administrator to do is simply acquiesce in the recommendations of her staff. The deference that courts properly owe to the political branches is captured, instead, by an unelected bureaucracy and outside science advisors due to the science charade.

## Summary

The NAAQS process exemplifies the incentives at work that compel every party to the regulation to engage in hidden policy judgment and the science charade. Congress directs EPA to set the standards to achieve noble goals, but encourages the politicization of science by restricting the agency from openly considering relevant nonscientific factors. Combined with tight deadlines, the statutory language permits Congress to take credit for laudable public goals, while blaming the executive branch's execution for any undesirable outcomes. The courts have reinforced a limited interpretation of the Act, as well as tight deadlines for issuing revised standards. Executive branch career and policy officials respond by hiding policy judgments and creating a science charade, developing scientific-sounding explanations to justify one standard over

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officials, the media, and the public with 'spin' on the science... with results distilled to the 'sound bite.'" Bachmann 2007: 687.

<sup>122</sup> For example, EPA faces a judicial deadline to issue final ozone NAAQS by October 15, 2015. <http://www.epa.gov/ttn/naaqs/standards/ozone/data/201404ozonenaqsorder.pdf>

<sup>123</sup> Fraas, Arthur. "Observations on OIRA's Policies and Procedures." *Administrative Law Review* Vol. 63, Special Edition: OIRA Thirtieth Anniversary Conference (2011), p. 86.

<sup>124</sup> Since the mid-1990s, the average interagency review time for NAAQS rules subject to deadlines was less than 20 days, compared to an average review time of more than 70 days for all EPA rules over the same period. Statistics can be derived from data available at [www.RegInfo.gov](http://www.RegInfo.gov).

another, and public interveners vigorously defend alternative standards based on their own interpretation of the “science.”

Scientists argue for the primacy of their data, analysts have an incentive to downplay rather than reveal uncertainties regarding their predictions or the implications of key risk assessment policy choices, and decision makers point to science as either requiring a new standard or as determining that existing standards are adequate.

This has evolved into an adversarial process, characterized by harsh rhetoric in which each party claims the science supports its preferred policy outcome and questions opponents’ credibility and motives, rather than a constructive discussion regarding appropriate data, assumptions and normative decisions. The real reasons for selecting a particular standard may not even be discussed. This harms the credibility of science advice and results in poorer decision making.

## Recommendations

Despite the National Research Council’s guidance over 30 years ago, controversy remains surrounding regulatory actions aimed at reducing risk, leading to accusations of “politicized science,” “advocacy science,” or “junk science.” What the NRC in 1983 identified as “a blurring of the distinction between risk assessment policy and risk management policy”<sup>125</sup> is enabled by the is-ought fallacy and leads to hidden policy judgments and science charades that harm policy outcomes and can damage faith in science itself.

In thinking about reforms to improve how science is used in developing regulations, clarifying which aspects of the decision are matters of science and which are matters of policy is essential to avoid both hidden policy judgments and the science charade. When people condemn the “politicization” of science,<sup>126</sup> the problem may really be that we ask too much of science in addressing policy problems. The Clean Air Act succumbs to the is-ought fallacy and does not permit transparent consideration of relevant policy factors when developing regulations. Other statutes, particularly those dealing with health, safety and the environment, are vulnerable to the same problem. As the BPC recommended, a focus of reform should be on devising regulatory processes that, “in as many situations as possible, ...help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy.”<sup>127</sup> This would not only help address the is-ought fallacy, but also the problem of hidden policy judgments, in which the effect of risk assessment policy judgments on estimates of outcomes are

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<sup>125</sup> National Research Council and the Committee on the Institutional Means for Assessment of Risks to Public Health. *Risk Assessment in the Federal Government: Managing the Process*. 1983. Washington D.C.: National Academies Press, p. 3.

<sup>126</sup> Mooney, C. *The Republican War on Science*. New York: Basic Books; 2006.

<sup>127</sup> Bipartisan Policy Center, 2009:4.



not acknowledged. “This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on, science.”<sup>128</sup>

Numerous experts have offered specific recommendations for improving the conduct of regulatory science. The recommendations that follow attempt to alter the incentives of the parties to the rulemaking process; the first category would address behavior contributing to the is-ought fallacy, the second would specifically address the problem of hidden policy judgments, and the third would improve incentives generally.

### Is-Ought Fallacy

The is-ought fallacy is the pretense that normative policy decisions regarding what “ought to be” can be determined exclusively by positive scientific information that describes what “is.” This mistake can lead to both hidden policy judgments in risk assessments and a science charade in justifying policy decisions. The first two recommendations aim to reduce incentives to succumb to the is-ought fallacy.

1. Legislators must be more forthright in recognizing that “science” is a positive discipline that can inform, but not decide, appropriate policy.

It would be challenging to convince legislators to avoid the is-ought fallacy and resist delegating decisions to agencies on the pretense that science alone can make the normative determination of what policy ought to be. This includes asking science advisors to recommend policy judgments they are typically ill-suited to provide. For legislators to make the effort to elevate the debate above simple rhetoric, they must have different incentives and expectations of rewards than exist now. Currently, there is no feedback loop to reward a politician for tackling these issues openly and seriously.

Comparing the effectiveness of different statutes can be illuminating, however. Some statutes directed at health, safety and environmental risks have facilitated more rational regulatory policy than others by recognizing that risk management requires normative judgments that consider tradeoffs. For example, the Safe Drinking Water Act requires EPA to consider the costs as well as the benefits of requiring local water authorities to install controls for specific substances. Perhaps that is one reason why the debates over drinking water standards are generally less acrimonious than debates over ambient air quality standards. Since the statute allows explicit consideration of tradeoffs when setting standards, the full burden of decision-making is not vested in the risk assessment. As a result, policy makers and interested parties may have less incentive to embed policy preferences in the risk assessment portion of the analysis, because they can debate them openly and transparently in the risk management discussion.<sup>129</sup>

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<sup>128</sup> Bipartisan Policy Center, 2009:5.

<sup>129</sup> Dudley & Gray, 2012.

Codifying current executive requirements for performing regulatory impact analyses, including benefit-cost analyses, could provide a “supermandate” that would require agencies to explicitly present uncertainties and tradeoffs and to justify decisions in a transparent manner.<sup>130</sup>

2. Legislators and policymakers must clarify the appropriate role for scientific advisors.

The engagement of scientific advisory panels can provide a necessary and valuable source of information and peer review for agency science, but greater efforts should be made to restrict their advice to matters of science, and not ask them to recommend regulatory policies. When asked to advise on policy choices, as is the case with CASAC, it is impossible for members not to be tempted to wrap their policy views in a lab coat and present them as scientific recommendations.<sup>131</sup>

As a former EPA scientist observed:

Scientific information must remain a cornerstone of public policy decisions, but I offer cautionary guidance to scientists: get involved in policy deliberations, but play the appropriate role. Provide facts, probabilities, and analysis, but avoid normative science. Scientists have much to offer the public and decision-makers, but also have much to lose when they practice stealth policy advocacy.<sup>132</sup>

Cox observes:

Experts, like other people, typically have high confidence in their own judgments, even when these lack objective validity.<sup>133</sup> But subjective confidence in subjective judgments should not be used in place of sound, objective scientific methods. To do so, as in EPA’s risk assessment for ozone, replaces sound science with potentially arbitrary, biased, and mistaken judgments.<sup>134</sup>

Legislators should be clear, when establishing committees like CASAC, to limit the role of scientific advisory panels to advising on science. Executive branch policy officials should also be

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<sup>130</sup> Dudley, Susan E. “Improving Regulatory Accountability: Lessons from the Past and Prospects for the Future.” *Case Western Reserve Law Review*. Vol 65. No. 1 (Summer 2015)

<sup>131</sup> See, for instance, the recommendation of former CASAC member Morton Lippman regarding changing the Clean Air Act. Lippman noted “CASAC’s role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues.” Dr. Morton Lippman. “Comments on the NAAQS Review Process.” 2006, at A-22.  
[http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo\\_0346-06/\\$File/sabso-casac\\_memo\\_and\\_comments.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/Vanessa%20Memo_0346-06/$File/sabso-casac_memo_and_comments.pdf)

<sup>132</sup> Lackey, 2013.

<sup>133</sup> Kahneman D. *Thinking Fast and Slow*. 2011. Farrar, Straus, and Giroux. New York, New York. (as cited in Cox 2014)

<sup>134</sup> Cox 2014.

very clear in drafting charge questions for advisory committees to solicit their scientific expertise without encouraging them to blur the lines between scientific expertise and policy judgment.<sup>135</sup> As both the BPC and Keystone reports emphasized, the questions posed to such panels “should be clearly articulated, and ‘explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics, and other matters of policy.’”<sup>136</sup> Experts with formal training and experience in policy analysis, economics, law, and other disciplines are much better equipped to provide advice on these latter questions.

## Hidden Policy Judgments

Risk assessment necessarily involves assumptions and judgments as well as pure scientific inputs, yet they often generate precise-sounding predictions that hide not only considerable uncertainty about the actual risk, but hidden policy judgements. When scientists, intentionally or unintentionally, insert, but do not disclose, their own policy preferences in the scientific advice they provide government decision-makers, it harms the credibility of science advice and results in poorer policy decisions.

3. The executive branch must establish procedures and incentives to make more transparent the effect different credible risk assessment inputs and assumptions have on the range of plausible outcomes.

This proposal reiterates the recommendations of expert reports issued over the last three decades, including recent recommendations from the Institute of Medicine<sup>137</sup> and BPC. One way to make the risk assessment policy choices more transparent to decisionmakers and the public would be for agency scientists to calculate and present multiple risk estimates based on a variety of scientifically plausible data sets, endpoints, models, *etc.*<sup>138</sup> This would be in stark contrast to the current practice in which agencies embed multiple risk assessment policy choices in a single assessment, which facilitates what one former EPA scientist calls “stealth advocacy... because the average person reading or listening to such scientific statements is likely unaware of the

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<sup>135</sup> Several former CASAC officials encouraged EPA to be clearer in its charge questions to distinguish between science and policy. Environmental Protection Agency Clean Air Scientific Advisory Committee (CASAC). CASAC Input on EPA’s revised NAAQS Review Process; 2006 March. Available at: <http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/NewNAAQSProcess?OpenDocument>

<sup>136</sup> The Keystone Center, 2012: 8. (Internal citation to BPC at 5.)

<sup>137</sup> See, for instance, recommendation 8.1 that “U.S. Environmental Protection Agency senior managers should be transparent in communicating the basis of its decisions, including the extent to which uncertainty may have influenced decisions.” at Board on Population Health and Public Health Practice; Institute of Medicine. *Environmental Decisions in the Face of Uncertainty*, Committee on Decision Making Under Uncertainty, 2013, p. 225. Available at: [http://www.nap.edu/catalog.php?record\\_id=12568](http://www.nap.edu/catalog.php?record_id=12568)

<sup>138</sup> Dudley & Gray 2012

underlying advocacy [and] ... hidden policy preferences.”<sup>139</sup> It is telling that currently, despite the fact the NAAQS level must “err on the side of safety,” EPA currently cannot (or will not) produce a quantitative estimate of just how prudent NAAQS levels are compared to more likely estimates of health risks.

Once a range of plausible risk outcomes is identified based on different scientifically plausible inputs, agencies could transparently identify which set of inputs, models, and outcomes comported with its preferred risk assessment policy choice. Policy officials would choose specific numerical values from a range of scientifically plausible risk estimates and publicly defend the risk assessment policy choices that support that choice. This would provide a serious incentive for policy officials to look into estimates of risk, consult with a broad variety of experts to understand the range of scientific views and explicitly articulate the policy preferences informing their decisions.

Greater transparency regarding the assumptions and policy rationales for choosing one set of assumptions or models over another would encourage more openness and constructive discussion about science and policy, improving the ultimate policy decision and probably engendering greater acceptance of that policy choice.<sup>140</sup>

4. The executive branch should institutionalize reforms that encourage greater feedback and challenge of risk assessment practices and policy choices.

Greater transparency in the models, assumptions, and risk assessment policy choices could encourage more open, constructive debate on those choices.<sup>141</sup> The scientific method depends on falsifiable hypotheses, data gathering, replication, dissent, and challenge, to ensure objective analysis to minimize bias in the interpretation of results.

No one is truly objective. We all approach problems with our own prior views and perceptions, and, particularly when faced with new or incomplete information, we tend to look to others in whom we trust to help form our opinions and make decisions. Research suggests that individuals form more extreme views when surrounded by others with similar perspectives.<sup>142</sup> Institutional reforms that intentionally engage, rather than avoid, competing views, could go a long way to improve the clarity of the risk assessment process and the decisions that depend on scientific input.

President Obama built on his predecessors’ efforts to provide for interagency review of different aspects of regulatory decisions, including the underlying science. He directed agencies to

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<sup>139</sup> Lackey, 2013.

<sup>140</sup> Dudley & Gray, 2012.

<sup>141</sup> Open Data Initiative <https://www.whitehouse.gov/open>

<sup>142</sup> Sunstein, 2009.

encourage an “open exchange of information and perspectives among State, local, and tribal officials, experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, ...including relevant scientific and technical findings.”<sup>143</sup>

Successful reforms might involve pre-rulemaking disclosure of risk assessment information, to engage broad public comment on the proper choice of studies, models, assumptions, etc. long before any policy decisions are framed, and “positions” established. Advanced notices of proposed rulemaking could be used effectively to gather such input.<sup>144</sup>

5. Scientific advisory panels should be required to represent a diversity of perspectives, disciplines, expertise, and experience.

The 2012 Keystone Center report offers a series of recommendations on “the composition of committees that are empaneled to review the science behind a regulatory decision.”<sup>145</sup> Acknowledging the importance of choosing panelists that “have the knowledge, training, and experience needed to address the charge to the panel,”<sup>146</sup> it admonished agencies “to recognize that all potential panelists will have conscious and unconscious biases,” and said that “the panel selection process requires review of the disclosed information and a judgment as to the ability of each prospective panelist to participate in open discussion and to consider other perspectives.”<sup>147</sup>

The report goes on to recommend:

Because biases exist, an agency should strive to engage a wide range of perspectives of qualified scientific experts. We endorse the BPC report’s statement that, “Agencies should not shy away from including scientists on a panel who are considered ‘outliers’ on the question(s) under consideration, provided that the scientist is a respected practitioner in a relevant field and the committee as a whole fairly represents the mainstream.”<sup>148</sup>

Former CASAC Chair George Wolff’s observations, quoted above, that the lack of balance among the individuals EPA empaneled to review the PM standards published in 2006

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<sup>143</sup> Obama, Barack. Executive Order 13563. “Improving Regulation and Regulatory Review.” 76 FR 3822 January 18, 2011.

<sup>144</sup> Balla, Steven J. and Dudley, Susan E. “Stakeholder Participation and Regulatory Policymaking in the United States.” A report prepared for the *Organisation for Economic Co-operation and Development*. 2014. <http://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/Balla-Dudley-US-Stakeholder-Reg-Process-11-2014.pdf>

<sup>145</sup> Keystone, 2012:4.

<sup>146</sup> Keystone, 2012:14

<sup>147</sup> Keystone, 2012:15

<sup>148</sup> Keystone, 2012: (quoting BPC at 24)

“predetermined the outcome of the review”<sup>149</sup> illustrates the effects on policy of not engaging a range of perspectives.

### Improving incentives for feedback, learning and experimentation

The scientific method involves forming a hypotheses, making predictions based on that hypothesis, and data gathering and empirical testing, followed by revisions to the hypothesis and predictions based on results. It represents a systems approach whereby feedback and challenge inform action and encourage learning. The recommendations that follow would improve incentives for feedback, learning and experimentation.

6. The legislative and executive branches should institutionalize feedback through retrospective review of regulatory outcomes.

Regulatory programs are rarely subjected to rigorous evaluation and feedback. Most regulatory analyses rely on models and assumptions to make predictions about the risk reduction benefits that will accrue from a specific intervention. Institutionalizing a requirement to evaluate whether the predicted effects of the regulation were realized would provide an incentive to improve the use of science for predicting the benefits of interventions.

President Obama’s executive orders directing agencies to review their regulations “to determine whether [they] should be modified, streamlined, expanded, or repealed so as to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives”<sup>150</sup> could facilitate better retrospective analysis. However, these and previous retrospective review guidelines have met with limited success, largely because they did not change underlying incentives.<sup>151</sup> For example, Section 812 of the Clean Air Act Amendments of 1990 requires EPA periodically to assess the benefits and costs of the Act,<sup>152</sup> but EPA’s assessment under this provision has relied on the same modeling it used for ex ante analysis, so it has not provided information necessary to validate estimates or underlying risk assessment assumptions and procedures.

A useful evaluation would measure population changes with respect to the predicted outcomes following the regulatory intervention. For example, actual reductions in cancer rates would be

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<sup>149</sup> Wolff, 2006.

<sup>150</sup> Executive Order 12866 (1993) and Executive Order 13563 (2011).

<sup>151</sup> Dudley, Susan E. *Testimony before the Joint Economic Committee: Reducing Unnecessary and Costly Red Tape through Smarter Regulations*, June 26, 2013, [http://regulatorystudies.columbia.gwu.edu/sites/regulatorystudies.columbia.gwu.edu/files/downloads/2013\\_06\\_26\\_Dudley\\_JEC\\_statement.pdf](http://regulatorystudies.columbia.gwu.edu/sites/regulatorystudies.columbia.gwu.edu/files/downloads/2013_06_26_Dudley_JEC_statement.pdf)

<sup>152</sup> EPA Office of Air and Radiation. *The Benefits and Costs of the Clean Air Act from 1990-2012: Summary Report*. Environmental Protection Agency; 2011 March. Available at: <http://www.epa.gov/oar/sect812/feb11/summaryreport.pdf>

compared to predicted reductions to determine if actual experience corroborates or challenges the hypothetical benefits. Cox offers concrete recommendations for applying statistical tools to test “how changes in inputs (such as exposure) propagate through a network of validated causal mechanisms to cause resulting changes in outputs (such as health effects).”<sup>153</sup>

Agencies should be required to include in proposed regulations a framework for empirical testing of assumptions and hypothesized outcomes. To incentivize more robust evaluation along the lines identified above, agencies could be required to test the validity of risk-reduction predictions before commencing new regulation that relies on models. The five-year NAAQS reviews, for example, could be required to apply quasi-experimental (QE) techniques to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions.<sup>154</sup>

Congress and OMB should reallocate resources from ex ante analysis to allow agencies to gather the information and evaluation tools necessary to validate ex ante predications. Shifting resources from ex ante analysis to ex post review would not only help with evaluation, but would improve our ex ante hypotheses of regulatory effects. Whether President Trump’s requirement<sup>155</sup> that agencies identify existing regulations to remove or modify before issuing new ones will lead to a shift in resources and motivate better retrospective analysis remains to be seen.

Retrospective review should not be left exclusively to regulatory agencies, which have little incentive to find fault with their regulations, but should be subject to third-party evaluation.<sup>156</sup> And, mechanisms such as sunset provisions, or offsets (as applied in other countries) could provide incentives for objective evaluation of regulations’ effects.<sup>157</sup>

#### 7. Regulations should be designed to facilitate natural experimentation and learning.

Designing regulations from the outset in ways that allow variation in compliance is essential if we are to go beyond observing mere associations and gather data necessary to test hypotheses of the relationship between regulatory actions, hazards, and risks. Quasi-experiments (QE), relying

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<sup>153</sup> Cox, 2015.

<sup>154</sup> Cox 2015, and Domenici, Greenstone & Sunstein, 2014

<sup>155</sup> Executive Order 13771 (2017).

<sup>156</sup> As Greenstone observed, “the process of self-evaluation is challenging for all organizations, as it requires complete objectivity. Indeed, history is unkind to organizations that fail to get outside reviews of their work.” Statement of Michael Greenstone, Milton Friedman Professor of Economics, University of Chicago, Director, Energy Policy Institute at Chicago, before the United States Senate Subcommittee on Regulatory Affairs and Federal Management Roundtable on “Examining Practical Solutions to Improve the Federal Regulatory Process.” June 4, 2015

<sup>157</sup> Dudley, Susan E. “Can Fiscal Budget Concepts Improve Regulation?” *NYU J. Legislation & Public Policy*. Vol. 19:259 (2016).

on differences in treatments (such as differences in attainment status with NAAQS) can inform risk assessments going forward.

QE evaluation techniques provide an opportunity to improve understanding of the relation between human health and particulates air pollution. In a QE evaluation, the researcher compares outcomes between a treatment group and a control group, just as in a classical experiment; but treatment status is determined by politics, an accident, a regulatory action, or some other action beyond the researcher's control. The key difference with an observational study in this setting is that the QE approach is devoted to identifying treatment-induced variation in particulates that plausibly mitigates confounding or omitted variables bias in the estimated relation between human health and particulates, rather than relying on the variation presented by nature and optimizing agents. Despite the "nonrandom" assignment of treatment status, it is possible to draw causal inferences from the differences in outcomes (by "outcomes," we refer to both air pollution levels and human health) between the treatment and control groups in a quasi- or natural experiment, provided certain assumptions are met.<sup>158</sup>

Agencies could conduct pilot studies or "deploy different regulations where empirical evaluations of such differences will help resolve disputed issues of regulatory policy."<sup>159</sup>

8. Greater weight should be placed on scientific studies that were subject to peer review and whose results are reproducible.

Peer review is often considered a fundamental component of the scientific process. Concerns over the extent and rigor of review of important scientific analyses led OMB in 2004 to issue a memorandum establishing guidelines for the use of external peer-review at all federal agencies and departments.<sup>160</sup> OMB has also directed agencies to issue information quality guidelines to, among other things, ensure the objectivity of information, including "a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."<sup>161</sup> These guidelines did not require reproducibility, however, observing that "reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination."

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<sup>158</sup> Domenici, Greenstone & Sunstein. 2014:258

<sup>159</sup> John O. McGinnis. *Accelerating Democracy: Transforming Governance through Technology*. Princeton University Press. 2012:311.

<sup>160</sup> U.S. Office of Management and Budget. 2004. *Information Quality Bulletin for Peer Review*. <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>

<sup>161</sup> U.S. Office of Management and Budget. 2002. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." 67 FR 8452



Scientific publishing is focusing more on the sharing of data and experimental transparency.<sup>162</sup> The journal *Science*, for example, has undertaken “initiatives to increase transparency and promote reproducibility in the published research literature... Connected to that progress, and an essential element to its success, an additional focus will be on making data more open, easier to access, more discoverable, and more thoroughly documented.”<sup>163</sup>

As the *Science* editors observe, “When the greatest number of creative and insightful minds can find, access, and understand the essential features that led to the collection of a data set, the data reach their highest potential.”<sup>164</sup> A greater emphasis on reproducibility can encourage challenge and validation so important to the scientific method.

9. Legislation should recognize that states have a core interest in environmental quality, and that experimentation and competition among states can be a powerful force for improving environmental outcomes and our practical knowledge of what works.

Many environmental statutes are structured, appropriately, with a prominent federalist framework. Much of the on-the-ground work is left to states, which makes sense because pollution is primarily a problem of local externalities, and also because local knowledge and local experimentation can be brought to bear on problems that are not susceptible to one-size-fits-all federal rules. As implemented, however, the NAAQS process assigns to EPA staff an artificial scientific determination, isolated from any practical considerations, and assigns to the states all of the problems of implementation, while depriving them of the policy discretion that might allow them to solve those problems. The resulting dynamic channels competitive energy into unproductive directions.

Perhaps a better division of responsibility would be for the federal government to conduct basic risk assessment research and share information on environmental damages, but defer to states or regional associations on decisions regarding the risk management policies appropriate for their situations. This would offer several advantages. First, it would help distinguish risk assessment from risk management, especially if combined with other recommendations aimed at avoiding the is-ought fallacy. Second, it would encourage risk management decisions to be made where they can best reflect the circumstances and preferences of affected citizens.<sup>165</sup> Third, the nation as a whole would gain from experimentation regarding how different policy measures work in practice, without imposing untried systems on the entire nation.<sup>166</sup> Such an approach would provide the natural experimental framework and data needed for more QE evaluation.

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<sup>162</sup> Joel Achenbach, “The new scientific revolution: Reproducibility at last.” *Washington Post*. January 27, 2015.

<sup>163</sup> *Science* 2 January 2015: Vol. 347 no. 6217 p. 7

<sup>164</sup> *Science*, January 2015.

<sup>165</sup> For pollutants that cross state borders, regional governance structures may be appropriate.

<sup>166</sup> Where there are large national economies of scope, such as the development of vehicle emission standards, the risk management could be done at the national level. Absent such economies, greater discretion on risk

10. Agencies should engage in collaborative tools to generate knowledge.

Nobel laureate Fredrich von Hayek identified the central problem facing public policy as “the unavoidable imperfection of man’s knowledge and the consequent need for a process by which knowledge is constantly communicated and acquired.”<sup>167</sup> Hayek’s focus was on economic planning and he showed that decentralized markets focus dispersed information—information that no one individual can obtain—and convey it efficiently to market participants. Many of the risks of concern to regulatory agencies may not be accounted for in market transactions, however. In these cases, we may require a different solution to address Hayek’s observation that relevant facts are never possessed by a single mind, to take advantage of knowledge “that is dispersed among many people.”

New media may provide a vehicle for stimulating a broader exchange of ideas and expanding our knowledge by reducing transaction costs, significantly lowering the costs of gathering and aggregating information, and removing obstacles to collaboration across a wide spectrum of individuals.<sup>168</sup> E-rulemaking provides a platform for following and commenting on federal regulations, but to date, it has mainly served to facilitate traditional notice and comment, and not generated interactive, iterative engagement.<sup>169,170</sup>

To harness the wisdom of dispersed knowledge, agencies or outside parties might experiment with a collaborative “wiki” approach to public comment, where, rather than each individual or group filing comments in parallel and the agency responding to those comments individually, it could provide a forum for diverse individuals to build on each other’s information, adding, editing, updating, and correcting to engage the wisdom of dispersed knowledge on issues where no one person has complete information.<sup>171</sup> Larry Sanger, founder of Wikipedia, calls this “distributed knowledge collaboration.”<sup>172</sup>

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management should remain with the states. Wallace E. Oates suggests that “the introduction in the 1970s and 1980s of a variety of emissions trading systems at the state level demonstrated the feasibility of such systems and some of their very appealing properties—as well as certain pitfalls.” He suggests that this state-level experimentation with innovative solutions to emissions problems led to the successful introduction of the national system of tradable sulfur allowances under the 1990 Clean Air Act Amendments. Oates, W.E. *Environmental Federalism. Resources for the Future (RFF)*; 2009. Available at: <http://www.rff.org/Publications/WPC/Pages/Environmental-Federalism-Wallace-E-Oates.aspx>

<sup>167</sup> Hayek F.A. 1945. “The use of knowledge in society.” *American Economic Review* 35, No. 4: 519-530.

<sup>168</sup> Shirky, Clay. *Here Comes Everybody: The Power of Organizing Without Organizations*. New York: Penguin Press. 2008.

<sup>169</sup> Dudley & Gray, 2012.

<sup>170</sup> Balla & Dudley, 2014.

<sup>171</sup> Dudley & Gray, 2012.

<sup>172</sup> Sanger, Larry “Toward a New Compendium of Knowledge.” 2006. <http://www.citizendium.org/essay.html>

One big advantage of a wiki approach is what Shirky calls its “publish-then-filter” model, where editing is done after something is posted, rather than before. Participants don’t need to worry that their post is incomplete or may have inaccuracies because other participants can expand or correct it.

In a system where anyone is free to get something started, however badly, a short, uninformative article can be the anchor for the good article that will eventually appear. Its very inadequacy motivates people to improve it; many more people are willing to make a bad article better than are willing to start a good article from scratch.<sup>173</sup>

Engaging public input through a wiki is an intriguing possibility that holds the potential to revolutionize how agencies gather information on which to base public policies.

## Conclusions

Institutional arrangements in the regulatory development process tend to aggravate two contributors to the politicization of science: “hidden policy judgments” (not acknowledging the policy judgments inherent in risk assessment) and “science charades” (camouflaging policy decisions as science). Both of these problems threaten the credibility of the scientific process and harm regulatory policy. Many of those involved in regulatory decisions have incentives to hide policy preferences, such as how to deal with the uncertainty in assessments of risk, and to dismiss and denigrate dissenting views. In many cases, politicization is the result of officials falling prey to the “is-ought fallacy” (incorrectly mixing up positive information about what “is” with normative advice about what “ought to be”). Key policy choices, disguised as science, too often rest with technical staff; meanwhile, policy makers charged with making hard policy decisions are able to avoid responsibility by claiming that their hands were tied by “the science.”

As a case study, this paper has examined the process by which EPA sets NAAQS under the Clean Air Act to illustrate some of the perverse incentives involved in developing regulations, and offered ten mechanisms to improve those incentives and resulting policy.

Effective environmental policy that focuses resources on addressing real threats to public health and the environment depends on reliable scientific information and transparent policy choices. The mechanisms offered here could reduce acrimony and improve the debate over environmental policy by helping distinguish between risk assessment and risk management, avoid the is-ought fallacy, and make more transparent previously hidden policy judgments. This will improve not only environmental outcomes, but the integrity of science advice.

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<sup>173</sup> Shirkey, 2008:122.

**To:** Greaves, Holly[greaves.holly@epa.gov]  
**Cc:** Dravis, Samantha[dravis.samantha@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]  
**From:** Kime, Robin  
**Sent:** Fri 6/30/2017 4:02:18 PM  
**Subject:** Questions for the Record assigned to OP  
OP Budget QFRs Final.docx

Hello,  
Attached are responses. I hope this is helpful. Just let us know if we can do more.  
Thank you.  
Robin

**From:** "Greaves, Holly" <greaves.holly@epa.gov>  
**Date:** June 27, 2017 at 1:45:09 PM EDT  
**To:** "Dravis, Samantha" <dravis.samantha@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>  
**Cc:** "Jackson, Ryan" <jackson.ryan@epa.gov>, "Lyons, Troy" <lyons.troy@epa.gov>  
**Subject:** Questions for the Record assigned to OP

Sam/Brittany,

We have received over 250 questions for the record from members of Congress related to the Administrator's House Budget Hearing. I'm writing to ask your help in crafting responses to 17 of the questions that deal with Policy matters.

Responses need to be returned to me and Troy **by noon on Friday** to meet the congressional deadline.

Attached please find the questions assigned to OP. Thanks in advance for your help!

Holly

**To:** Bolen, Brittany[bolen.brittany@epa.gov]  
**From:** Kime, Robin  
**Sent:** Thur 6/15/2017 5:16:27 PM  
**Subject:** RE: For your review by tomorrow 12:00 a.m. please: Responds to QFRs from May 19 House E&C drinking water hearing

Thank you- will have it revised and resubmitted to you.

**From:** Bolen, Brittany  
**Sent:** Thursday, June 15, 2017 1:15 PM  
**To:** Kime, Robin <Kime.Robin@epa.gov>  
**Subject:** RE: For your review by tomorrow 12:00 a.m. please: Responds to QFRs from May 19 House E&C drinking water hearing

Hello,  
The first response needs to be consistent with all the summaries we have provided on EO 13771 – above all – where is the mention of the progress report?

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thank you.  
Brittany

**From:** Kime, Robin  
**Sent:** Thursday, June 15, 2017 8:06 AM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Cc:** Lovell, William <lovell.william@epa.gov>  
**Subject:** For your review by tomorrow 12:00 a.m. please: Responds to QFRs from May 19 House E&C drinking water hearing

Good morning,  
OCIR received a set of Questions for the Record from a May 19 House Energy & Commerce drinking water hearing. We sent in a statement for the record for that hearing in lieu of a witness, and we offered to take QFRs. The QFRs have arrived. OCIR asks that we submit answers to the two questions below. Sarah and Bill drafted these answers below. With your edits, I'll share them with OCIR by their deadline of noon tomorrow. Thanks and have a good day.

6. What steps has EPA taken to implement President Trump's Executive Order on Reducing Regulation and Controlling Regulatory Costs?

# Deliberative Process / Ex. 5

a. How is EPA choosing which two regulations to repeal for every new regulation promulgated?

# Deliberative Process / Ex. 5

| Line Number | Current Language | Requested Revision to Language | Rationale for Request |
|-------------|------------------|--------------------------------|-----------------------|
|-------------|------------------|--------------------------------|-----------------------|

**Streamlining Permitting and Reducing Regulatory  
Burdens for Domestic Manufacturing v14**

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## 1. Executive Summary

In writing this report, the role of the Department of Commerce (Department) is to amplify the point of view of the domestic manufacturing community to ensure that manufacturers' concerns are fully understood and openly addressed by federal regulators. While it is incumbent upon regulators to consider the views of all stakeholders, the manufacturing sector deserves special consideration as the Administration embarks on regulatory reform as a critical component of its economic agenda. The numerous enthusiastic and thorough responses to the RFI reflect the sentiment within the business community that, for too long, their views have not been heard. There is a vital need for better dialogue and understanding between regulators and the regulated community. While the business views expressed in the report may differ from those of regulators and other stakeholders, the fact that manufacturers continue to raise the same concerns indicates a failure on the federal government's part to fully engage and effectively work with the businesses community it is regulating.

### Recommendations

The Department recommends that each agency's Regulatory Reform Taskforce (RRTF) review *all* relevant detailed comments received in response to the Department's request for information<sup>1</sup> (RFI) and deliver an "action plan" to the administration not later than September 30, 2017. Action plans should outline proposals to address outstanding issues identified in this report or justify why action cannot or should not be taken. Agency action plans should pay particular attention to correcting perceived burdens in the following Areas of Emphasis list as well as those identified in Section 5b of this report. Items on these two priority lists were distilled from hundreds of submissions and selected for special emphasis due to their massive economic impact on industries throughout the economy. Each agency's RRTF should prioritize a response to these particular items and must include in their action plan a description of specific actions which could be taken to lessen the burden created by them. In the first year, agency leadership should update the President monthly on the status of their efforts regarding these tasks. While these lists are by no means comprehensive, they represent a targeted first step to quickly address the problem of over regulation.

In addition, the Department recommends creating an annual, open forum between industry leaders and all federal regulatory agencies to evaluate progress. There is a long overdue need for consultations with industry to determine where regulatory burdens are becoming most oppressive and to isolate specific

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<sup>1</sup> <https://www.regulations.gov/docket?D=DOC-2017-0001>; docket ID DOC-2017-0001



actions the federal government can take to reduce onerous regulations and hasten permitting. Industry has repeatedly expressed its appreciation of the Trump Administration's regulatory reform effort and the trust it has in the Department of Commerce to listen and bring businesses' voice to this effort. Because of this, the Department of Commerce recommends that it, along other regulatory agencies, continually evaluate progress and re-attack the problem areas. Similar to Kentucky's "Red Tape Reduction Initiative", federal agencies should collect, review, and act on recommendations from industry. Input from these annual "check-ins" will guide the continuing burden reduction efforts of RRTFs and ensure regulators are moving in the right direction while allowing for course changes as needed.

Finally, to further advance recent successes with expediting permitting, the Department recommends expansion of the definition of projects that qualify as "covered projects" under Title 41 of the Fixing America's Surface Transportation Act (FAST Act or "Fast 41")<sup>2</sup> to include: "projects the construction of which will result in a significant, immediate economic benefit to the United States." Immediate economic benefit could be defined as funded projects which are ready for groundbreaking within 24-48 months where sponsors can demonstrate direct and indirect benefits to the domestic economy of greater than \$200 million. The exact definition could be refined further by OMB in consultation with the Federal Permitting Improvement Steering Council (FPISC). The FAST Act contains various provisions aimed at streamlining the environmental review process, with improved agency coordination through creation of a Coordinated Project Plan and a Permitting Dashboard which serves as a centralized information page for pending projects, as well as opportunities to better coordinate with state environmental documentation. Expansion of the definition of covered projects to include those which result in immediate economic benefit to the United States would help to further goals of expanding the domestic economy and lessening permitting burdens for manufacturers seeking domestic expansion of their operations.

The Department believes that these three recommendations, if executed promptly and with constant, aggressive leadership will yield outsized results.

#### Economic Cost of Regulations

It is well established that federal regulations represent a significant cost to the economy. Estimates vary, and range up to nearly \$2 trillion,<sup>3</sup> but most agree that the manufacturing sector is disproportionately

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<sup>2</sup> 42 USC §41003 et seq.

<sup>3</sup> W. Mark Crain and Nicole V. Crain, "The Cost of Federal Regulation to the U.S. Economy, Manufacturing, and Small Business" National Association of Manufacturers, September 2014

burdened. The direct costs, estimated by the National Association of Manufacturers (NAM) to be \$138.6 billion as of 2014,<sup>4</sup> do not include indirect negative effects on the U.S. economy such as reduced innovation and global competitiveness, investment hesitancy, opportunity costs and global offshoring. As further evidence of the extraordinary costs of regulatory burden the Manufacturers Alliance for Productivity and Innovation estimated in a 2012 report that the U.S. experienced a loss of gross domestic product (GDP) ranging from \$240 billion to \$630 billion<sup>5</sup>. Also, based on input, it would appear that small firms bear a disproportionate burden due to their scale disadvantage. Comments universally underscored that the federal government underestimates compliance costs it places on businesses resulting from individual regulations and their cumulative effect.

## Findings

The urgency for reform continues to grow. A 2017 NAM study found that most manufacturers perceive their regulatory burden to have increased significantly, such that reducing their current burden is more imperative than reducing the cost of new regulations.<sup>6</sup> Through submitted comments, industry expressed clear support for the need to protect the environment, human health, and worker safety, but shared concrete, detailed concerns with how the federal government has set out to achieve those objectives through regulation, guidance documents, and other means. They identified numerous regulatory and permitting problems that include:

- Onerous and lengthy permitting processes that increase cost, add uncertainty, and inhibit investment in and expansion of manufacturing facilities;
- Inadequately designed rules that are impractical, unrealistic, inflexible, ambiguous or lack understanding of how industry operates;
- Unnecessary aspects of rules, or unnecessary stringency, not required to achieve environmental or other regulatory objectives;
- Overlap and duplication between permitting processes and agencies; and
- Overly strict or punitive interpretations of guidance, policies or regulations that is often counter to a pro-growth interpretation.

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<sup>4</sup> National Association of Manufacturers, "The Cost of Federal Regulation to the U.S. Economy, Manufacturing and Small Business"

<sup>5</sup> NERA Economic Consulting, "Macroeconomic Impacts of Federal Regulation of the Manufacturing Sector", Manufacturers Alliance for Productivity and Innovation," August 21, 2012

<sup>6</sup> National Association of Manufacturers, "Holding US Back: Regulation of the U.S. Manufacturing Sector", Pareto Policy Solutions, LLC

The Department identified ##### sets of regulations and permitting issues as being a top priority for reform and immediate action. Consistent with previous studies on the costs of federal regulations, comments on Environmental Protection Agency (EPA) rules dominated the responses from industry.<sup>7</sup> EPA's New Source Review – a pre-construction clean air permitting regulation – was frequently cited as the most burdensome permitting requirement.

Despite numerous regulatory reform initiatives over the years, and yet business continues to express concerns about growing regulatory burdens. Prior reform efforts have prescribed reasonable principles for effective rulemaking, including the use of cost-benefit analysis (CBA), examining alternatives to regulations, and retrospective reviews. These principals have had limited success. Political will across the federal government and agencies has been lacking, as have clear, transparent, public metrics of progress. Executive Order (EO) 13771<sup>8</sup> and EO 13777<sup>9</sup> create the much needed metrics and organizational structures to achieve success. This report compiles input and begins to create a dialogue with the manufacturing sector, which has also been lacking.

Factors that have undermined prior reform efforts include: debate over cost-benefit models, methodologies and assumptions; a lack of agency resources and incentives to comply fully with all rulemaking requirements; and a lack of power and resources in oversight organizations to compel compliance with these principles. Even where required and completed, the effects of mandating CBAs do not ensure the most cost-beneficial regulatory alternative is selected. These assessments can fail to capture the true costs of implementing regulation. Currently, agencies have an inherent bias to generate an analysis that supports their preferred alternative and therefore are likely to make assumptions that cast their pending rule in a favorable light. Only when independently verified and used to prevent promulgation of cost prohibitive rules are they able to contribute to regulatory cost control efforts.

Based on numerous examples of unnecessary, unreasonable, outdated or impractical requirements regulators do not appear to embrace a philosophy of “least burden.” Rather, the federal requirement to “maximize net benefits” prescribed in EO 12866<sup>10</sup> leaves the door open for compounding addition of regulations, assuming “net benefits” can be demonstrated using the aforementioned CBAs, which are easily manipulated. Only by improving the way agencies work *with* the regulated community

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<sup>7</sup> See Section 5c and Appendix 4 for a detailed discussion and list of prior studies.

<sup>8</sup> 82 FR 9339, Pages: 9339-9341; <https://www.federalregister.gov/d/2017-02451>

<sup>9</sup> 82 FR 12285, Pages 12285-12287, <https://www.federalregister.gov/d/2017-04107>

<sup>10</sup> EO 12866, <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>

(manufacturers in this case), *before and after* a rule is promulgated can the “real-world” impacts of their regulatory burdens be addressed. The previous statement pre-supposes that regulatory agencies strive to avoid promulgating rules which will levy overly cumbersome constraints and costs on manufacturers. This intangible component of culture can only be influenced by agency leadership.

In short, multiple issues have stymied prior reform efforts. Long-term government leadership and emphasis will need to be applied to make progress in lessening regulatory burden.

#### Background

On January 24, 2017, President Trump signed a Presidential Memorandum on *Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing*, in which he required the Secretary of Commerce to conduct outreach to stakeholders on the impact of federal regulations and permitting requirements on the U.S. manufacturing industry. In coordination with other executive departments and agencies, the Secretary was tasked with delivering this report, setting forth a plan to streamline federal permitting processes for domestic manufacturing and reducing the regulatory burdens thereof. This report reflects extensive, thoughtful comments received from U.S. manufacturers as well as upstream and downstream industries closely linked to the manufacturing sector. It synthesizes comments from the manufacturing sector and provides recommendations for immediate action. It also provides recommendations to create a mechanism for recurring feedback, through which, industry can provide input on the regulatory and permitting burden it faces, and mechanisms for that input to lead to concrete actions by federal regulatory agencies. One such concrete action recommended by this report should be a progress update by regulatory agencies to the President within 90 days of publication of this report.

The Presidential Memorandum directing this report is one part of an Administration-wide regulatory reform agenda. President Trump has issued several Executive Orders (EO) that provide impetus and direction for regulatory reform efforts. These include EO 13771 on *Reducing Regulation and Controlling Regulatory Costs*, which directs departments and agencies to identify for elimination at least two regulations for every one new regulation issued; EO 13777, *Enforcing the Regulatory Reform Agenda*, which requires agencies to designate a Regulatory Reform Officer (RRO) who is responsible for overseeing regulatory reform initiatives, and to establish a Regulatory Reform Task Force (RRTF); and EO 13683 which directs agencies to review regulations affecting the domestic energy industry and to appropriately reduce undue burdens to the development of domestic energy resources. For this report, the Department sought input from a wide swath of the American industrial base through a formal RFI issued in the Federal Register. The RFI

165 (Appendix 2) asked industry to identify the most burdensome regulations and permitting requirements they  
166 face and requested feedback on how regulatory compliance and permitting could be simplified. This report  
167 aggregates and summarizes the most important recommendations raised by industry and presents the  
168 Department's recommendations to address these problem areas.

169 Scope

170 This report focused on regulatory and permitting issues that directly impact the construction, operation or  
171 expansion of manufacturing plants. While focused on the manufacturing sector, upstream and downstream  
172 industries also submitted comments echoing the concerns of U.S. manufacturers and highlighting unique  
173 issues that they face. This report includes that input because regulatory barriers that adjoining industries  
174 face can weaken production and investment in the domestic manufacturing sector.

Areas of Emphasis: Select Industry Recommendations // Ongoing or required corrective actions.

**Clean Air Act (CAA)**

1. New Source Review (NSR) or Prevention of Significant Deterioration (PSD) permits:
  - a. Enforce the one-year turnaround time on NSR/PSD permit applications. // EPA will coordinate with state and local air agencies, as well as EPA regional offices, to develop best practices, guidance, or regulatory revisions necessary to ensure that NSR permits are issued consistent with the 12-month timeline described in the CAA.
  - b. Reduce statute of limitations on challenges or appeals to one year. // EPA is pursuing regulatory action intended to streamline the Title V process. Congressional action would be required to reduce statute of limitations.
  - c. Allow non-emitting construction activities to commence prior to receiving a permit. // EPA would need to review existing regulations and guidance and identify situations for which it would be appropriate to provide additional clarity and/or opportunities to begin construction without a PSD permit.
  - d. Consider options to revise the definition of Routine Maintenance, Repair & Replacement (RMRR) to provide more flexibility. // Statutory change would be required.
  - e. Promote and facilitate use of flexible permitting mechanisms associated with PSD and Title V including, but not limited to, plant-wide applicability limits (PALs) and alternative operating scenarios. As part of this, consider any regulatory or other changes (e.g., guidance) that could facilitate more widespread use of these flexible permitting tools. // EPA could conduct outreach to educate sources and permitting agencies on benefits of flexible permitting tools and also consider minor changes to PAL provisions to provide more incentives for sources to use PALs. The EPA intends to highlight and encourage use of flexible air permitting options.
  - f. Consider opportunities to streamline NSR applicability determinations and/or to reduce the number of facilities and projects that may be subject to NSR through evaluating and pursuing regulatory and guidance options for addressing aggregation, project netting, debottlenecking, and the methodology by which pre and post construction emissions are calculated. // EPA should review existing regulations and guidance to identify opportunities

to address these issues and provide more flexibility through regulatory actions. Litigation is pending over EPA's 2009 aggregation and project netting rule; this litigation is pending resolution of EPA's reconsideration process.

- g. Issue guidance on modeling concurrent with promulgation of revised National Ambient Air Quality Standards (NAAQS), to ensure timely clarification on modeling required as part of a NSR application. // EPA has committed to timely issuance of guidance.
- h. Consider opportunities to "grandfather" NSR applications following revision of a NAAQS. // Existing regulations provide some opportunities for "grandfathering" NSR applications.
- i. Consider opportunities to emphasize key aspects of the Best Available Control Technology (BACT) analysis including, but not limited to, expectations regarding technology determinations. // EPA would need to evaluate what could be provided to streamline BACT determinations.
- j. Consider opportunities to expand opportunities for purchasing offsets outside of the local areas as well as other offset related revisions which would provide increased flexibility and burden reduction.

- 2. Title V Operating Permits (incorporates all of the federal and state air pollution control requirements). Extend the term of the permit from 5 to 10 years. // The EPA is completing the petitions rulemaking will revise part 70 to clarify and streamline the process by which EPA receives and reviews Title V petitions, thereby increasing transparency and efficiency for regulated entities, environmental agencies. This action will address how EPA intends to review Title V petitions in an effort to reduce opportunities to raise NSR issues in the context of Title V. The EPA has proposed non-regulatory approach in its proposed draft report revisions.

- 3. National Emissions Standards for Hazardous Air Pollutants (NESHAP):

- a. EPA should increase efforts to consider opportunities to reduce costs and avoid duplicative requirements in conducting reviews of NESHAP standards.
- b. EPA should take steps to ensure that any new requirements considered under Residual Risk and Technology Reviews (RRTRs) would not be redundant or unreasonably costly. // Under its existing authorities EPA is taking action to harmonize NESHAP and NSPS obligations.

- 237
- 238 4. Consider options to provide relief for facilities through affirmative defenses or other avenues to
- 239 account for unforeseeable and uncontrollable emissions during periods of startup, shutdown, and
- 240 malfunction (SSM). The EPA previously adopted an interpretation which exempted SSM periods
- 241 from the emissions restrictions that apply under normal operating periods. // Pending litigation<sup>11</sup>.
- 242
- 243 5. National Ambient Air Quality Standards (NAAQS):
- 244 a. EPA should consider options for considering "real world measurements" versus
- 245 "probabilistic models" for the PSD program. // The EPA is concerned that this approach
- 246 would result in a directive that would impose greater costs on regulated facilities. This
- 247 issue is similar to many raised in the NSR/PSD suggestion.
- 248 b. Extend NAAQS revisions from 5 to 10 years. // Altering the NAAQS timeframe would
- 249 require congressional action. EPA should consider opportunities to ensure that any
- 250 forthcoming reviews are not redundant and are completed expeditiously.
- 251 c. Ozone: Delay implementation of the 70 parts per billion (ppb) standard or retain the current
- 252 75 ppb standard - Observers claim the 70 ppb level is approaching "background" levels of
- 253 ozone.<sup>12</sup> The pace at which the standard has been tightened is too rapid, and is further
- 254 complicated by measurement and air quality modeling issues – in particular accounting for
- 255 ozone transported from international sources.
- 256
- 257 6. Consistent with its authorities under section 111 of the CAA, EPA should consider adding
- 258 exemptions for R&D related activities or otherwise streamline requirements for R&D activities for
- 259 New Source Performance Standards promulgated under Section 111 of the CAA. // EPA is
- 260 evaluating its authority to exempt R&D related activities under section 111. The EPA has routinely
- 261 considered adding exemptions for R&D related activities and has added specific R&D exemptions
- 262 in the past<sup>13</sup>.
- 263

---

<sup>11</sup> Pending litigation in *Walter Coke, Inc., et al. v. EPA*, No. 15-1166 (D.C. Cir.) (challenge to SSM SIP) and in *American Municipal Power v. EPA* (Sup. Ct.). Whether such exemptions and affirmative defenses can be allowed under the CAA is central to the litigation.

<sup>12</sup> On-going litigation: *Murray Energy Corporation et al. v. EPA*, No. 15-1385 (and consolidated cases), (D.C. Cir.) (challenge to the 2015 ozone NAAQS).

<sup>13</sup> See 40 CFR sections 60.40(c) and (d); 60.292(d); and 60.332(h)



7. EPA should issue a Unified Coating Rule (UCR) that facilities could choose to meet (replacing the eight overlapping NSPS and NESHAP regulations that apply to coatings)<sup>14</sup>. // EPA should consider options with an UCR to provide flexibility that encourages facilities to meet the rule by using pollution prevention approaches.

### **Clean Water Act**

8. Waters of the U.S. Rule – define more narrowly “waters of the US” to exclude ephemeral tributaries. EPA and the U.S. Army Corps of Engineers (USACE) are reviewing the existing Clean Water Rule and its definitions of “navigable waters” as directed by Executive Order 13778. // The EPA is undertaking a two-step process to revise the definition of Waters of the US. The first proposal that is part of that two-step process is currently (as of May 17) undergoing interagency review.

9. Section 404<sup>15</sup> and NPDES permits: provide permit applicants with clear descriptions of required steps and additional tools to assist them in completing the permitting process. // EPA and USACE should explore opportunities to truncate the permitting processes and elevate any barriers, such as needed regulatory changes, to senior leadership for consideration.

### **Other**

10. Resource Conservation and Recovery Act (RCRA): Inappropriate classifications of waste streams as “hazardous” prevent or discourage recycling, reuse or reclamation. Aggressively review lists of hazardous waste to consider delisting certain compounds/materials/liquids that could easily be reused or recycled, but for this classification. // In 2015 EPA published a comprehensive revision to its rules governing the recycling, reuse and reclamation of hazardous secondary materials, where these materials would otherwise become listed or characteristic hazardous wastes if discarded rather than recycled.

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<sup>14</sup> There is ongoing litigation regarding several NESHAP. EPA cannot provide specifics. EPA has court ordered deadlines to complete risk and technology reviews for several NESHAP that apply to certain coatings.

<sup>15</sup> Section 404 Permits is under the purview of the US Army Corps of Engineers.

- 293 11. Rescind the new Crystalline Silica Standard. In 2016 an Occupational Safety and Health  
294 Administration (OSHA) rule was finalized which cut in half the permissible exposure to crystalline  
295 silica (for general industry and maritime) from 100 to 50 micrograms per cubic meter.  
296 Recommendation is to keep allowed level at 100 micrograms per cubic meter. // Could be modified  
297 or repealed by agency notice-and-comment rulemaking. Must remain consistent with underlying  
298 statutory provisions in the Occupational and Safety and Health Act<sup>16</sup>. Pending litigation.  
299
- 300 12. Revise the Rule to Improve Tracking of Workplace Injuries and Illnesses by removing requirement  
301 to disclose records of workplace injuries and illnesses and to alleviate the duplicative nature of  
302 work-related injury information collection. Clarify in guidance that this rule should not undermine  
303 safety incentives and drug testing programs. // Could be modified through further notice-and-  
304 comment rulemaking (underlying statutory requirement that companies maintain certain injury  
305 records).  
306
- 307 13. Revise Section 1502 of Dodd-Frank Act. Remove the requirement on manufacturers to “*undertake*  
308 *‘due diligence’ on the source and chain of custody of its conflict minerals and file a Conflict*  
309 *Minerals Report*” and to disclose publicly this information. // This would require a statutory change.  
310
- 311 14. Rescind Section 953(b) of Dodd Frank Act which requires CEO pay ratio disclosure. // This would  
312 require a statutory change.  
313
- 314 15. Do not implement expanded requirements for hours and earnings data on EEO-1 forms. //  
315 Changes could be made administratively, but would have to be done in compliance with the  
316 Paperwork Reduction Act (PRA).  
317
- 318 16. Delay compliance dates for Intentional Adulteration rule required by the Food Safety Modernization  
319 Act (FSMA). Rescind requirements to obtain written assurances from downstream customers on  
320 an annual basis, or alternatively consider revision of requirement to reduce frequency and burden.  
321 // Administrative action would be required to effect a delay in the compliance dates for the  
322 Intentional Adulteration rule. Although FSMA required that FDA promulgate a final rule to protect  
323 food against intentional adulteration within 18 months of enactment of FSMA, the statute does not

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<sup>16</sup> 29 U.S.C. § 655(b)(5)

324 appear to specify compliance dates<sup>17</sup>. Delaying compliance would require publishing a final rule;  
325 rescinding or revising the written assurance provisions would require rulemaking.

326  
327 17. Extend compliance deadline on nutrition labeling standards from 2018/2019 to 2021. This will  
328 allow further time for FDA to further clarify rules<sup>18</sup> and definitions regarding “dietary fiber” and  
329 “added sugar” required by the new label format. // Administrative action would be required to  
330 extend the compliance date for this rule.

---

<sup>17</sup> The current compliance dates are 3,4 or 5 years after the date of publication of the rule (May 27, 2016), depending on the size of the business

<sup>18</sup> The rule was promulgated pursuant to section 403(q) of the Federal Food, Drug, and Cosmetic Act, which requires certain nutrients to be included in nutrition labeling and authorizes the Health and Human Services Secretary to require other nutrients to be included if the Secretary determines that the information will assist consumers in maintaining healthy dietary practices.

## 2. Introduction

On January 24, 2017, the White House issued a Presidential Memorandum on *Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing* (see Appendix 1). The memorandum requires the Secretary of Commerce to submit a report to the President offering a plan to address these issues, after soliciting public comments from stakeholders and coordinating with other executive departments and agencies.

There are several Executive Orders (EO) from the Administration which provide additional direction for regulatory reform efforts. Executive Order 13771, issued on January 30, 2017, on *Reducing Regulation and Controlling Regulatory Costs*, directs departments and agencies, for fiscal year 2017, to identify for elimination at least two regulations for every one new regulation issued or proposed. Moreover “any new incremental costs associated with new regulations... shall be offset by the elimination of existing costs associated with at least two prior regulations, such that total incremental costs are no greater than zero.” For fiscal years 2018 and beyond, agencies will be provided a regulatory “budget,” which defines the total “incremental costs that will be allowed for each agency in issuing new regulations and repealing regulations for the next fiscal year... The total incremental cost allowance may allow an increase or require a reduction in total regulatory cost.” (Note that these requirements do not apply to “regulations issued with respect to a military, national security, or foreign affairs function of the United States.”)

On April 5, 2017, the Office of Management and Budget (OMB) issued Memorandum M-17-21, providing guidance and details regarding EO 13771. Significant clarifications include:

- The two-for-one requirement does not apply to independent agencies
- Costs should be measured as “the opportunity cost to society” as defined in OMB Circular A-4
- “Agencies should also confirm that they will continue to achieve their regulatory objectives after the deregulatory action is undertaken.”
- “Effects such as future energy cost savings for rules that require the adoption of more energy efficient technologies” would generally not be counted as “offsets to costs according to OMB’s Office of Information and Regulatory Affairs’ (OIRA) reporting conventions for benefit-cost analysis.”
- That two-for-one requirement “is to provide a mechanism for agencies to identify and repeal outdated, ineffective, or unnecessary regulatory actions.”
- definitions of regulatory and deregulatory actions.

A second Executive Order, 13777, *Enforcing the Regulatory Reform Agenda*, was issued on February 24, 2017. This EO requires agencies to designate a Regulatory Reform Officer (RRO), who is responsible for overseeing regulatory reform initiatives and policies, and to establish a Regulatory Reform Task Force (RRTF), which is charged with evaluating existing regulations and making “recommendations to the agency head regarding their repeal, replacement, or modification.” Specific regulatory reform policies referenced in the EO, which the RRO and RRTF will be responsible for implementing include:

- EO 13771 (referenced above), regarding offsetting the number and cost of new regulations;
- EO 12866 of September 30, 1993 (Regulatory Planning and Review), regarding the regulatory planning and review process;
- EO 13563, Section 6 of January 18, 2011 (Improving Regulation and Regulatory Review), regarding enhancement of retrospective review and analysis of existing regulations.

RRFT are instructed to focus on regulations that “inhibit job creation”, are “outdated, unnecessary, or ineffective”, or “impose costs that exceed benefits”. The EO includes a requirement for the RRFT to report on progress within 90 days (May 25, 2017) from the date of the order.

### 3. Methodology

The conclusions presented in this report were developed using filtering criteria such as:

- Literature review and secondary research
- RFI and resulting public comments
- Public outreach through the Manufacturing Extension Partnership’s (MEP) National Advisory Board
- Listening session with the National Association of Manufacturers
- Outreach to other governmental regulatory agencies by the Department of Commerce

#### 3a. Literature review and secondary research

Existing studies, reports, data and articles on regulatory burden and reform initiatives were collected and summarized to develop a baseline understanding of:

- The regulatory burden imposed on manufacturers
- Attempts at quantifying the impact of regulatory burden on the economy and costs for manufacturers
- The history of regulatory reform initiatives and approaches to reform
- Existing federal permitting requirements and processes that impact manufacturers

– Specific regulatory or permitting challenges or issues that impact manufacturers

Based on this research, the research team also developed a framework for categorizing responses to the RFI, and identified an initial set of specific regulatory or permitting issues which could be combined with the issues raised in response to the RFI.

### *3b. RFI*

The Department of Commerce requested input from stakeholders such as manufacturers, trade associations, and other interested parties through a RFI, which was published in the Federal Register on March 7, 2017. The comment period was closed on March 31, 2017. The Department received 176 total comments. Six of the comments received were either incomplete or duplicates of earlier submissions and not included in the analysis. As a result, 170 were incorporated into the conclusions of this report.<sup>19</sup>

The RFI requested input on: “how the construction, operation, and expansion of domestic manufacturing facilities are affected by (1) the process of acquiring Federal permits required for the construction, expansion, or operation of such facilities and (2) the burdens of complying with Federal regulations for manufacturing facility construction, expansion, or operation.” The complete RFI text is included in Appendix 2. All comments were read by the research team. The information in the comments was also reviewed and analyzed via a natural language software analysis tool. Responses were searched by agency, regulation, permit and legislation to identify the most frequently mentioned of these and allow the research team to identify more quickly the most relevant responses.

### *3c Information Session with Manufacturing Extension Partnership (MEP) National Advisory Board*

Mr. Earl Comstock from the Department’s Office of Policy and Strategic Planning (OPSP) chaired a discussion with MEP’s National Advisory Board at the Board’s meeting on March 7, 2017 at DOC. The Board provides advice to the National Institute of Standards and Technology (NIST) Director under the provisions of the Federal Advisory Committee Act. Members represent large and small manufacturers, community colleges, and universities. During the hour-long discussion with the Board, Mr. Comstock led them through the questions that are in the RFI. Their responses are summarized in the minutes of the Board meeting, included in Appendix 3.

### *3d. Coordination with Regulatory Agencies*

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<sup>19</sup> All relevant comments received in response to the RFI have been made available publicly at <http://www.regulations.gov>.

The Department also conducted outreach to regulatory agencies, both those mentioned specifically in the Memorandum and those not mentioned but that regulate one or more aspects of manufacturing. A meeting with the agencies was held on March 28, 2017, chaired by Mr. Comstock. Agencies represented included the Departments of Agriculture (USDA), Commerce (DOC), Health and Human Services (HHS), Interior, Labor (DOL) and Transportation (DOT), the Environmental Protection Agency (EPA), the Federal Communications Commission (FCC) and the Small Business Administration (SBA). A representative from OMB was also present.

Seven agencies or components of agencies (EPA, Department of Labor [DOL], Department of Energy [DOE], HHS/Food and Drug Administration [FDA], DOT/Pipeline and Hazardous Materials Safety Administration [PHMSA], FCC, and SBA) provided written comments regarding their roles in regulation and permitting, including actions they are taking to review and reduce unnecessary regulation and/or streamline permitting processes. EPA and DOL also received a list of the key issue areas identified by the commenters, given the large number of comments specifically directed at those two agencies, and each agency has provided initial responses to those comments. Appendix 4 includes comments from those seven agencies.

Although not often thought of as a regulatory agency or cited frequently by commenters, the Department of Commerce also has a regulatory role through some of its bureaus. Overall, the Department issues almost 400 proposed or final rules each year, making it one of the more active federal regulatory agencies. The vast majority of these (approximately 250) are National Oceanic and Atmospheric Administration (NOAA) rules related to the management of fisheries. The National Marine Fisheries Service (NMFS) within NOAA promulgates these rules in accordance with the Magnuson-Stevens Fishery Conservation and Management Act. Under that law, the Regional Fishery Management Councils made up of industry, community and NGO representatives develop the content of the regulations which NMFS then implements. The changing fishing seasons and dynamic statistical data on the health of each fishery drive the pace and content of these regulations. NMFS works closely with the fishing community to keep them apprised of changes in the rules. The Bureau of Industry and Security (BIS) is the second most active regulatory bureau within the Department. This bureau issues regulations regarding sensitive and cutting edge technology that enhance our national security while ensuring that U.S. manufacturers and technology companies remain competitive and innovative. BIS evaluates costs and benefits of loosening or tightening controls on specific types of technology in light of present day threats and current trends in the economic

and technological landscape. Department of Commerce regulations or processes were mentioned in nine instances across eight comments. Appendix 4 provides responses from NOAA and BIS, as well as the U.S. Patent and Trademark Office (USPTO) and the International Trade Administration (ITA).

### *3e. Definitions of Regulatory Burden*

This report has defined regulatory burden as “an increase in manufacturers’ costs, or missed opportunities for growth, expansion, or investment, resulting from onerous regulatory and permitting processes.” More specifically, the focus of this effort is on *unnecessary costs*<sup>20</sup> that can be avoided without undermining regulatory objectives, such as environmental stewardship or worker health and safety. This in part emerges from the RFI responses, which in general did not object to regulatory objectives, but rather raised concerns that specific regulatory approaches were unnecessary or inconsistent in application to achieve these benefits. There are many opportunities to reduce regulatory burden without compromising governmental objectives. The second point is that this definition is somewhat simpler than (though not inconsistent with) OMB Circular A-4 which provides a primer on regulatory impact cost-benefit analysis. The definition in this report, we believe, is also consistent with the way manufacturers view the impact of regulatory burden on their business.

## **4. Background**

Executive agencies are delegated the power to regulate by Congress, through broad grants of authority or in specific statutes that direct agencies to regulate certain areas, such as occupational health and safety or clean air. Under the Administrative Procedure Act (APA),<sup>21</sup> enacted in 1946, Congress established procedural requirements for implementing public policy as set forth in statutes.<sup>22</sup> In addition to rulemaking, agencies also publish interpretive rules and general policy statements, often in the form of guidance documents and enforcement manuals. These non-rulemaking actions can serve many purposes, such as clarifying vague language in regulations to ensure consistent interpretations among agency staff. However, these actions do not require the same procedures as rulemaking, and the resulting documents, if treated as de facto regulations, can avert the transparency and accountability of the rulemaking process.<sup>23</sup>

<sup>20</sup> There will certainly be disagreement about what is an unnecessary cost. However, this report strives to focus on those burdens that the RFI responses identified as unnecessary.

<sup>21</sup> Administrative Procedure Act, 5 U.S.C. §§551-559.

<sup>22</sup> See Stuart Shapiro, “Agency Oversight as “Whac-a-Mole”: The Challenge of Restricting Agency Use of Nonlegislative Rules,” *Harvard Journal of Law and Public Policy*, Spring 2014, vol. 37, issue 2, 523-552.

<sup>23</sup> John Graham and James Broughel, “Stealth Regulation: Addressing Agency Evasion of OIRA and the Administrative Procedure Act” (June 1, 2014). *Harvard Journal of Law and Public Policy, Federalist Edition*, June 2014, vol. 1, issue 1, 30-54.



The White House, primarily through the Office of Management and Budget (OMB), provides oversight over regulatory agencies. This role is intended to ensure that agencies follow certain “principles of good policymaking,” including identifying the problem the agency is seeking to solve through regulation (such as addressing a market failure), identifying alternative ways to resolve the problem (including non-regulatory options), and using a cost-benefit framework to evaluate those alternatives. This oversight role also applies to the recent emphasis on retrospective analysis of the cumulative impact of regulations and periodic reporting on efforts to reduce regulatory burdens.

For decades, regulatory activity has been accompanied by efforts at reform designed to minimize regulatory burden for U.S. businesses. Fundamentally, reforms have been intended to ensure that regulators are accountable to the public and that technical expertise drives regulatory decision-making. Recently, President Trump has re-invigorated efforts at regulatory reform by exercising the expedited regulatory streamlining process contained in the Congressional Review Act of 1996 (CRA).<sup>24</sup> The CRA requires regulatory agencies to submit rules to Congress prior to them taking effect and allows Congress to review and disapprove of the regulations.<sup>25</sup> Over the past two decades, the CRA process was successfully used to disapprove of only one regulation, in 2001. This year, fourteen regulations have been repealed using this mechanism.

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<sup>24</sup> Congressional Review Act, 5 U.S.C. §§801-808.

<sup>25</sup> Under the CRA, an agency must submit a report to Congress and the Comptroller General containing a copy of the rule, a general statement that identifies whether it is a major rule, and the rule’s proposed effective date. Upon receipt, Congress has specified time periods to submit and act on a joint resolution of disapproval. If both houses pass it, the resolution is sent to the President for signature or veto. A rule so disapproved may not be issued in substantially the same form. See Maeve P. Carey, Alissa M. Dolan, Christopher M. Davis, “The Congressional Review Act: Frequently Asked Questions” Congressional Research Services, R43992, November 17, 2016.

| <b>Regulatory Disapprovals Signed into Law Under the Congressional Review Act</b> |                   |                                                 |                                                                                                                           |
|-----------------------------------------------------------------------------------|-------------------|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| <b>Public Law</b>                                                                 | <b>Date</b>       | <b>Regulatory Agency</b>                        | <b>Subject of Disapproved Rule</b>                                                                                        |
| Pub.L. 107-5                                                                      | March 20, 2001    | Dept. of Labor                                  | Ergonomics                                                                                                                |
| Pub.L. 115-4                                                                      | February 14, 2017 | Securities and Exchange Comm.                   | Disclosure of Payments by Resource Extraction Issuers                                                                     |
| Pub.L. 115-5                                                                      | February 16, 2017 | Dept. of Interior                               | Stream Protection                                                                                                         |
| Pub.L. 115-8                                                                      | February 28, 2017 | Social Security Admin.                          | NICS Improvement Amendments Act of 2007                                                                                   |
| Pub.L. 115-11                                                                     | March 27, 2017    | Dept. of Defense, General Services Admin., NASA | Federal Acquisition; Fair Pay and Safe Workplaces                                                                         |
| Pub.L. 115-12                                                                     | March 27, 2017    | Dept. of Interior                               | Resource Management Planning                                                                                              |
| Pub.L. 115-13                                                                     | March 27, 2017    | Dept. of Education                              | Accountability and State Plans Under Elementary and Secondary Education Act of 1965                                       |
| Pub.L. 115-14                                                                     | March 27, 2017    | Dept. of Education                              | Teacher Preparation Issues                                                                                                |
| Pub.L. 115-17                                                                     | March 31, 2017    | Dept. of Labor                                  | Drug Testing of Unemployment Compensation Applicants                                                                      |
| Pub.L. 115-20                                                                     | April 3, 2017     | Dept. of Interior                               | Non-Subsistence Take of Wildlife, and Public Participation and Closure Procedures, on National Wildlife Refuges in Alaska |

|                   |                |                                          |                                                                                                                                          |
|-------------------|----------------|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Pub.L. 115–<br>21 | April 3, 2017  | Dept. of Labor                           | Clarification of Employers’<br>Continuing Obligation to Make and<br>Maintain an Accurate Record of<br>Each Recordable Injury and Illness |
| Pub.L. 115–<br>22 | April 3, 2017  | Federal<br>Communications<br>Comm.       | Protecting the Privacy of Customers<br>of Broadband and Other<br>Telecommunications Services                                             |
| Pub.L. 115–<br>23 | April 13, 2017 | Dept. of Health<br>and Human<br>Services | Compliance With Title X<br>Requirements by Project Recipients<br>in Selecting Subrecipients                                              |
| Pub.L. 115–<br>24 | April 13, 2017 | Dept. of Labor                           | Savings Arrangements Established<br>by Qualified State Political<br>Subdivisions for Non-Governmental<br>Employees                       |

489

490

491 *4a. Scope of Regulations Reviewed in this Report*

492 This report focuses on the impact of regulations and permitting processes affecting domestic  
493 manufacturing. While much of the literature on regulatory reform initiatives and approaches applies  
494 generally to all regulations and rule-making, this report focuses its attention on regulatory and permitting  
495 issues that directly impact manufacturing operations, i.e., the construction, operation or expansion of  
496 manufacturing plants, or where manufacturing businesses are disproportionately affected. The report also  
497 considered regulatory and permitting issues affecting upstream and downstream industries whose  
498 operations are closely linked to the domestic manufacturing sector. The analysis also included some  
499 economy-wide regulations that were not particularly or disproportionately focused on manufacturing, such  
500 as the overtime rule.

501

502 *4b. Economic Costs*

503 There is general agreement that businesses bear a significant cost in complying with federal regulations,  
504 although businesses recognize the meaningful benefits from regulation as well. Cost estimates vary widely,

from roughly \$100 billion<sup>26</sup> (using a bottom-up approach to sum the costs of individual regulations) to nearly \$2 trillion<sup>27</sup> (using a top-down approach to include the aggregate impact of regulations on the economy). By one estimate, regulatory costs constrain economic growth by 0.8 percentage points per year.<sup>28</sup> These cost estimates are eye-opening, but they are based on very different estimation methods and are, at best, imprecise.<sup>29</sup> According to the Congressional Research Service (CRS) “estimating the total cost of regulations is inherently difficult. Current estimates ... should be viewed with a great deal of caution.”<sup>30</sup> While the precise estimates of regulatory costs may be disputed, studies suggest that the manufacturing sector is disproportionately burdened.<sup>31</sup> In a 2017 study, the National Association of Manufacturers (NAM) found that in the Code of Federal Regulations “715 parts... contain nearly 300,000 restrictions on domestic manufacturing” and in a 2014 study, NAM estimated the annual direct cost of federal regulations on the manufacturing sector to be \$138.6 billion.<sup>32</sup> Furthermore, cost calculations may not consider other business impacts of regulation that manufacturers consider important, such as: resources reallocated from innovation to compliance; additional entry barriers for new firms; reduced competitiveness against global firms who do not bear the same regulatory burdens; and investment disincentives caused by regulatory uncertainty, including investment offshoring.

Not only do manufacturers bear a significant regulatory burden, it is widely recognized that *small* firms can be disproportionately affected. According to NAM, firms with fewer than 50 employees have regulatory costs per employee that are 2.5 times<sup>33</sup> the costs of firms with more than 100 employees. Although there is some dispute about this claim,<sup>34</sup> there is little doubt that larger firms enjoy a scale advantage in complying with new regulations.<sup>35</sup>

In a 2017 NAM survey, “72% of manufacturer respondents believed their regulatory burden had increased “significantly” within the past five years. The accumulated existing burden is perceived to be so great that

<sup>26</sup> “In 2014 dollars, aggregate annual ... costs [were] between \$74 and \$110 billion. These ranges reflect uncertainty in the ... rule at the time that it was evaluated.” (OMB, “2016 Draft Report”)

<sup>27</sup> W. Mark Crain and Nicole V. Crain, “The Cost of Federal Regulation to the U.S. Economy, Manufacturing, and Small Business” National Association of Manufacturers, September 2014

<sup>28</sup> Bentley Coffey, Patrick A. McLaughlin and Pietro Peretto, “The Cumulative Cost of Regulations”, Mercatus, April 2016

<sup>29</sup> Ted Gayer and Philip Wallach, “Prospects for regulatory reform in the Trump administration”, Brookings, December 20, 2016

<sup>30</sup> Maeve P. Carey, “Methods of Estimating the Total Cost of Federal Regulations”, Congressional Research Service, January 21, 2016

<sup>31</sup> OMB/OIRA, “Progress in Regulatory Reform: 2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities”, 2004

<sup>32</sup> \$215 billion for direct and indirect costs. (NAM, “Cost of Federal Regulation”)

<sup>33</sup> And 33% more for Medium sized manufacturers. (NAM, “Cost of Federal Regulation”)

<sup>34</sup> RFF, “Grading Estimates”

<sup>35</sup> Pareto Policy Solutions, “Holding US Back: Regulation of the U.S. Manufacturing Sector” National Association of Manufacturers, January 2017

75% of the respondents “*prefer reducing the cumulative burden of existing regulations*” versus reducing the cost of new regulations,<sup>36</sup> a sentiment supported by previous industry analysis.<sup>37</sup>

Underlying all these studies is a criticism, echoed repeatedly in comments from industry, that the federal government frequently underestimates the costs of complying with its regulations and fails to consider the cumulative costs of compliance. Although regulatory agencies consider the costs of their regulations on a rule by rule basis, some argue that the accumulated burden of “layers” of regulations is greater than the sum of the individual regulation costs.<sup>38</sup> A NERA/MAPI report explains that “*This super-additive result occurs because the regulations interact with each other and create additional distortions in the economy, leading to higher costs and impacts.*”<sup>39</sup> The permitting process represents one way in which regulations might “interact” to compound regulatory burdens. In particular, large projects that involve permit applications with multiple regulatory agencies may be subject to redundancies and delays. A recent analysis documented several examples of project delays and suggested that delays in construction on public projects resulted in trillions of dollars in additional costs.<sup>40</sup>

The agency that is frequently cited as imposing the greatest number of regulations and regulatory cost burden on the manufacturing sector is the Environmental Protection Agency (EPA). A 2012 report indicates that, of major regulations (which are the ones that are more likely to have cost estimates), EPA-imposed regulatory costs on the manufacturing sector were \$117 billion (in constant 2010 dollars) – by far the highest of any agency – followed by the Departments of Transportation, Health and Human Services, and Homeland Security, which each imposed between \$7 billion and \$25 billion in annual regulatory costs.<sup>41</sup>

The same 2012 report found that EPA accounted for almost half the 2,200 unique regulations issued since 1981. In a NAM study, manufacturers themselves perceive that the greatest federal regulatory cost pressures are related to environmental/health/safety, tax, and labor.<sup>42</sup>

It is important to recognize that this review of regulatory costs does not consider the benefits of regulations. Nevertheless, evidence of the high regulatory costs borne by manufacturers underscores the need for regulatory reform to identify ways to reduce these burdens, and enact them expeditiously while preserving the benefits.

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<sup>36</sup> NAM, “Holding US Back”

<sup>37</sup> NERA Economic Consulting, “Macroeconomic Impacts of Federal Regulation of the Manufacturing Sector”, Manufacturers Alliance for Productivity and Innovation, August 21, 2012

<sup>38</sup> Mercatus, “Cumulative Cost”

<sup>39</sup> NERA/MAPI, “Macroeconomic Impacts”

<sup>40</sup> Philip K. Howard, “Two Years Not Ten Years: Redesigning Infrastructure Approvals” Common Good, September 2015.

<sup>41</sup> NERA/MAPI, “Macroeconomic Impacts”

<sup>42</sup> NAM, “Holding US Back”

553

554 *4c. Past Attempts at Regulatory and Permitting Reform*

555 *By the late 1970's, an array of federal economic and social regulations were in place that*  
 556 *affected many of the decisions made by American businesses. Strong concerns then*  
 557 *began to be raised about whether the benefits that these regulations and regulatory*  
 558 *agencies were attempting to achieve were worth the costs associated with compliance.*  
 559 *Concerns were also being raised about the cumulative effects of all federal regulations on*  
 560 *individual businesses.<sup>43</sup>*

561 Over the years there have been many regulatory reform efforts – some have been Congressional Acts,  
 562 many were Executive Orders. A list of major reforms by category is included in Appendix 5. These lists are  
 563 not meant to be comprehensive, but illustrate decades of effort - and raise questions about reform efficacy,  
 564 which will be addressed in Section 6. What follows is an outline of reform categories which provides  
 565 context on a number of basic ways to address the problem.

566

| Common Regulatory Reform Categories                                         |                                                                                                                                                                               |
|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type of reform                                                              | Description                                                                                                                                                                   |
| A. Analysis Best Practices                                                  | Establish an efficient and effective rule, best practices in analysis of the rule are necessary (e.g., cost-benefit analysis, using best science, and examining alternatives) |
| B. Retrospective Review;<br>Regulatory Lookback                             | Examining existing rules provides real data to assess costs, benefits, and unanticipated effects (versus models used <i>ex ante</i> )                                         |
| C. Establishing Oversight /<br>Watchdog Organizations and<br>Defining Roles | Includes entities outside of the regulatory agencies focused on good rule making and regulatory reform and serving as a clearinghouse for regulatory information              |
| D. Public Engagement;<br>Transparency                                       | Agency collaboration with or input from groups that will be affected by regulation, before rules are put in effect; Ensuring transparency in the rulemaking process           |

<sup>43</sup> Curtis W. Copeland, "Federal Regulatory Reform: An Overview", Congressional Research Service, April 20, 2004

|                                             |                                                                                                                    |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| E. Reduce Waste and Inefficiency in General | Although all reforms seek to reduce inefficiency, these reforms in this category specifically target this issue    |
| F. Special Consideration for Small Business | Special consideration for the impacts on small businesses must be given in developing and implementing regulations |
| G. Permitting                               | Reforms related to permitting                                                                                      |

567

568 *A. Analysis Best Practices.* Given the significant economic cost of some regulations, it is not surprising that  
569 many reforms have focused on requiring that rules are created utilizing the best possible analysis.  
570 Appendix 5A lists 10 Acts, Executive Orders and OMB circulars that require or encourage agencies to  
571 analyze the cost and benefits of regulations issued by the federal government. The list includes guidance  
572 that dates from 1981 to 2011, a period of time covering seven Administrations. In addition to *quantifying*  
573 costs and benefits these reforms require assessing *qualitative* costs and benefits, cumulative costs, and the  
574 impacts on innovation, as well as the use of the best available science and analytical tools. Regulatory  
575 reforms also have required the consideration of alternatives – including market-based incentives (rather  
576 than a command and control approach). Despite the long list of reforms in this category, even a basic cost-  
577 benefit analysis is not required for all federal regulations.<sup>44</sup> Even when these assessments are completed,  
578 they are not effective in reducing regulatory burden.

579 *B. Retrospective Review/Regulatory Look-back.* Retrospective analyses – using actual outcomes versus  
580 estimates – are critical in striving for the least burdensome regulations that will yield the desired objective.  
581 Many reforms have included requirements for regulatory lookback and yet reports support the claim that the  
582 “number of *ex post* analyses of regulations remains small, despite being highly valued”.<sup>45</sup> The seven Acts  
583 and Executive Orders on the list in Appendix 5B cover a period from 1979 to 2012 and eight  
584 Administrations. They not only dictate that agencies conduct retrospective analyses but some provide  
585 guidance on how to conduct those analyses.

<sup>44</sup> For example independent regulatory agencies are not required to provide a cost-benefit analysis. (CRS, “Methods of Estimating”)

<sup>45</sup> Winston Harrington, “Grading Estimates of the Benefits and Costs of Federal Regulation”, Resources for the Future, September 2006; other reports include: Paul R. Noe, “Smarter Regulation for the American Manufacturing Economy,” American Forest & Paper Association, (presented at the US Manufacturing and Public Policy Conference, September 14, 2016); Richard Williams, “The Impact of Regulation on Investment and the U.S. Economy”, Mercatus, January 2011

586 *C. Establishing Oversight/Watchdog Organizations and Defining Roles.* According to the Mercatus Center  
587 at George Mason University, agencies lack impartiality in reviewing their own regulations<sup>46</sup> and an outside  
588 watchdog is needed “to keep agencies on track [and] to ensure that bureaucracies follow the spirit as well  
589 as the letter of the law”.<sup>47</sup> This sentiment is supported by the list of reforms in Appendix 5C going back  
590 decades that require regulatory oversight of issuing agencies’ analyses and compliance with reforms, and  
591 that establish various taskforces to tackle regulatory reform from an outside perspective.

592 *D. Public Engagement; Transparency.* There is often an adversarial relationship between some regulatory  
593 agencies and groups that are affected by regulations. In a recent National Association of Manufacturers’  
594 survey, the most common response by manufacturers to a query about the difficulty of complying with  
595 regulations was that they are written without “adequate understanding of my business and my compliance  
596 challenges.” NAM recommends that “particular emphasis should be placed on enhanced public  
597 engagement prior to the writing of a proposed rule so regulators can best understand the businesses they  
598 aim to regulate, and businesses can find out which new regulations are coming their way.”<sup>48</sup> Many Acts and  
599 Executive Orders have addressed this issue. The nine included in Appendix 5D date back to 1935 and  
600 provide a variety of ways and guidance on how agencies should interact with the public.

601 *E. Reduce Waste and Inefficiency in General.* While there may be disagreements over the objective of a  
602 regulation or a regulatory approach, “it is generally accepted that [“the regulatory burden in its various  
603 forms”] should be the minimum necessary to accomplish the rules’ objectives,”<sup>49</sup> and all reform efforts  
604 (including those discussed in other categories) seek to reduce waste and inefficiency in some form. Over  
605 time some reforms have specifically targeted inefficiency, redundancy, and waste while other types have  
606 actually added regulatory burden that has little value. The six Acts and Executive Orders listed in Appendix  
607 5E, beginning with the Paperwork Reduction Act of 1980, demonstrate a long history of attempting to  
608 eliminate unnecessary burdens.

609 *F. Special Consideration for Small Businesses.* Given the importance of supporting and nurturing small  
610 businesses, there have been many reforms that seek to identify and mitigate the regulatory burden on  
611 these entities. The six Acts and Executive Orders listed in Appendix 5F show attempts since 1980 to  
612 mitigate these burdens but are not prescriptive as to how the agencies might accomplish this goal.

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<sup>46</sup> [www.mercatus.org/publication/how-well-do-federal-regulations-actually-work-role-retrospective-review](http://www.mercatus.org/publication/how-well-do-federal-regulations-actually-work-role-retrospective-review)

<sup>47</sup> Mercatus, “Impact of Regulation”

<sup>48</sup> NAM, “Holding US Back”

<sup>49</sup> CRS, “Federal Regulatory Reform”



*G. Permitting.* The four Acts, Executive Orders and other guidance listed in Appendix 5G relate to federal permitting of infrastructure projects, which indirectly affects the manufacturing sector. However, guidelines and best-practices embedded in these infrastructure-related permitting reforms may help inform reforms of federal permitting more commonly experienced by manufacturers, such as those related to EPA's New Source Review (part of the Clean Air Act).

## **5. Specific Regulatory and Permitting Issues**

### *5a. Regulatory and Permitting Problems – Key Themes*

This section discusses priority regulatory and permitting issues that were identified from the RFI responses, the meeting with the MEP board and the literature review.<sup>50</sup> Before delving into each of these issues individually, this section outlines some of the key themes and cross-cutting problems that emerge throughout these examples. In most cases, RFI respondents and the MEP Board did not question the need to protect the environment, human health or worker safety – but expressed concern about the regulations employed to achieve those objectives. Collectively, the RFI and Board responses identified a series of regulatory and permitting problems that include:

- Onerous and lengthy permitting processes that increase cost, add uncertainty, and inhibit investment in and expansion of manufacturing facilities;
- Inadequately designed rules that are impractical, unrealistic, inflexible, ambiguous or lack understanding of how industry operates;
- Unnecessary aspects of rules, or unnecessary stringency, not required to achieve environmental or other regulatory objectives;
- Overlap and duplication between permitting processes and agencies; and
- Overly strict or punitive interpretations of guidance, policies or regulations that is often counter to a pro-growth interpretation.

A more detailed set of regulatory problems by category is shown below.

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<sup>50</sup> These themes emerge from our analysis of the RFI responses, and previous reports on regulatory reform related to manufacturing, including: OMB/OIRA, "Regulatory Reform of the Manufacturing Sector", 2005; NAM, "Holding US Back"; Mercatus, "Impact of Regulation"; Sofie Miller, "EPA's Retrospective Review of Regulations: Will It Reduce Manufacturing Burdens?", Regulatory Studies Center at George Washington University, *Engage* 14, no. 2 (July 2013)

| Category               | Problem                                                                                                                                                                                                                                 | Examples from RFI Responses                                                                                                                 |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Inadequate Rule Design | A regulation is written or implemented with a lack of “on the ground” knowledge about how the regulated industry operates <sup>51</sup> , is economically or technologically infeasible, or is based on unrealistic data or assumptions | NAAQS Ozone standard – unrealistic assumptions on background levels;<br>Crystalline Silica Exposure Standard                                |
|                        | There is a lack of clarity around the requirements needed to comply with the regulation                                                                                                                                                 | CWA – Definition of Waters of the U.S.                                                                                                      |
|                        | The regulation is inflexible or too prescriptive. Overly strict interpretations of policy and guidance.                                                                                                                                 | NSR – inflexibility in aggregating emissions within a plant, so it does not trigger NSR                                                     |
|                        | Overlap or, duplication of rules                                                                                                                                                                                                        | NSPS and NESHAP overlap                                                                                                                     |
|                        | A better regulatory approach exists to achieve the objectives or the approach actually undermines key regulatory objectives                                                                                                             | RCRA –inappropriate classification of certain waste streams as hazardous, which has perverse effect of discouraging recycling of this waste |
|                        | The regulation is outdated                                                                                                                                                                                                              | Leak Detection and Repair Rules – outdated monitoring technology options                                                                    |
|                        | Regulatory over-reach – goes beyond statute or rulemaking                                                                                                                                                                               | NSPS enforcement beyond rules                                                                                                               |
|                        | Complex, onerous, inefficient and lengthy processes, particularly permitting processes                                                                                                                                                  | NSR Permitting Process                                                                                                                      |
|                        | Uncertainty, particularly permitting processes                                                                                                                                                                                          | Section 404 Wetlands Permitting process (wide variation in duration)                                                                        |

<sup>51</sup> In response\* to the following question: “The most challenging regulations to comply with are due to \_\_\_\_\_, the statement that most commonly represented the experience of manufacturers surveyed by NAM (41.7% of responses) was “regulatory agencies writing a final rule absent an adequate understanding of my business and my compliance challenges.” (NAM, “Holding US Back”)

|                                                                  |                                                                                                                           |                                                                                                                   |
|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Cumbersome Processes – Particularly Onerous Permitting Processes | Overlap, duplication or poor coordination between agencies, rules or permits                                              | Title V permitting decisions can be a basis for “re-litigating” decisions already made under NSR pre-construction |
|                                                                  | Inconsistency, among agencies or between federal and state regulatory authorities, in application or enforcement of rules | CAA permits – EPA often intervenes in state decisions                                                             |

639

640 This specific list of regulatory problems is important, because it points toward new opportunities to reduce  
641 regulatory or compliance burden in different types of regulations. It forces regulators and businesses to ask:  
642 how could the rule design be improved while still achieving the benefit of regulation? How could processes  
643 be less cumbersome? Are the costs too high to justify the benefits?

#### 644 *5b. Selection of Priority Specific Regulatory and Permitting Issues*

645 The selection of priority regulatory and permitting issues in this section, was based on the following criteria:

- 646 – The volume of responses citing a particular issue (see table below)
- 647 – The number of in-depth or broad scope responses that discussed the issue
- 648 – Comments in the responses that highlighted an issue as of particular importance in terms of  
649 regulatory burden or estimated costs; for example, NSR/PSD was often singled out as the most  
650 significant regulatory and permitting burden, and the ozone NAAQS standard and crystalline silica  
651 exposure standard were both highlighted as resulting in very high costs (table below)
- 652 – Issues that were discussed in sufficient detail to identify the nature of the burden and point toward  
653 potential solutions and actionable recommendations<sup>52</sup>
- 654 – Based on the literature review, some issues were included (or considered) because they have  
655 been longstanding challenges

656

657 As discussed in Section 4a., this report focuses its attention on regulatory and permitting issues that  
658 directly impact the construction, operation or expansion of manufacturing plants. The next section (5c)

<sup>52</sup> As an example, though there were numerous concerns expressed about recent changes to the Toxic Substances Control Act (TSCA), resulting from the Lautenberg Chemical Safety Act, the responses did not coalesce around a specific set of issues or recommendations.

659 offers an individual discussion of select issues. While some of these regulatory issues primarily affect the  
 660 manufacturing sector, others affect businesses across multiple sectors. Several issues not making this list  
 661 are highlighted in Section 5c below due to their indirect impacts on manufacturing, a perceived high level of  
 662 adverse impact on economic growth and the factors identified above.

| <b>Most Frequently Mentioned Regulatory &amp; Permitting Issues that Impact Manufacturing</b> |                       |                                                                                      |                     |
|-----------------------------------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------------------------|---------------------|
|                                                                                               | <b>Federal agency</b> | <b>Issue area</b>                                                                    | <b># Commenters</b> |
| 1                                                                                             | EPA                   | CWA: Wetlands Permits and Waters of The U.S.                                         | 42                  |
| 2                                                                                             | EPA                   | CAA: National Emissions Standards for Hazardous Air Pollutants (NESHAP)              | 41                  |
| 3                                                                                             | EPA                   | CAA: New Source Review and Prevention of Significant Deterioration Permits (NSR/PSD) | 40                  |
| 4                                                                                             | EPA                   | CWA: National Pollutant Discharge Elimination System (NPDES) Permits                 | 31                  |
| 5                                                                                             | EPA                   | CAA: Greenhouse Gas Requirements                                                     | 29                  |
| 6                                                                                             | EPA                   | CAA: National Ambient Air Quality Standards (NAAQS) (general)                        | 28                  |
| 7                                                                                             | EPA                   | Resource Conservation and Recovery Act (RCRA)                                        | 18                  |
| 8                                                                                             | EPA                   | Risk Management Programs and Reduced Risk and Tech Review                            | 19                  |
| 9                                                                                             | EPA                   | Toxic Substance and Control Act (TSCA)                                               | 18                  |
| 10                                                                                            | DOL                   | Improve Tracking of Workforce Injuries and Illnesses                                 | 14                  |
| 11                                                                                            | DOI and DOC           | Endangered Species Act                                                               | 13                  |
| 12                                                                                            | SEC                   | Conflict Minerals Rule (Dodd-Frank)                                                  | 12                  |
| 13                                                                                            | EPA and others        | National Environmental Policy Act                                                    | 11                  |
| 14                                                                                            | EPA                   | Regional Haze Requirements                                                           | 10                  |
| 15                                                                                            | DOL                   | Crystalline Silica Exposure                                                          | 10                  |
| 16                                                                                            | DOL                   | Overtime Rule                                                                        | 9                   |
| 17                                                                                            | EPA                   | Comprehensive Environmental Response, Compensation & Liability Act (CERCLA)          | 9                   |

|    |      |                                                 |   |
|----|------|-------------------------------------------------|---|
| 18 | EPA  | Spill Prevention, Controls, and Countermeasures | 9 |
| 19 | EEOC | EEO-1 Form                                      | 7 |
| 20 | HHS  | Food Safety Modernization Act                   | 5 |

The next section of this report, highlights specific regulatory issues of high importance, while most of the items correspond with the above list, some do not. Items selected for further discussion below were selected based on perceived importance from the totality of our review and not exclusively due to the number of mentions received in response to our public request. References to specific responses have been cited in parentheses in the text, as opposed to in footnotes. Appendix 6 lists the specific responses cited, the response number, and the short-hand name or abbreviation used in these citations.

#### *5c. Priority Regulatory and Permitting Issues*

##### *5c.1. CWA: Wetland Permits and Waters of the U.S. (WOTUS) Rule*

As part of the Clean Water Act (CWA), the EPA regulates discharges of pollutants into “waters of the U.S.” As described by the EPA:

*The term “water of the United States” is... defined very broadly in the Clean Water Act and after 25 years of litigation. It means navigable waters, tributaries to navigable waters, interstate waters, the oceans out to 200 miles, and intrastate waters which are used: by interstate travelers for recreation or other purposes, as a source of fish or shellfish sold in interstate commerce, or for industrial purposes by industries engaged in interstate commerce.<sup>53</sup>*

The Clean Water Rule<sup>54</sup>, promulgated in 2015, was perceived by many respondents to have expanded the definition of waters of the U.S. – or at least added ambiguity to its definition – in ways that extend federal authority beyond the traditional limits. However, different sources describe the expanded scope in different ways. NAM states that it “*extend(s) federal jurisdiction of CWA programs well beyond traditional navigable waters to ephemeral tributaries, flood plains, adjacent features and vaguely defined ‘other waters.’... For manufacturers, the uncertainty of whether a pond, ditch or other low-lying or wet area near their property is*

<sup>53</sup> [www.epa.gov/npdes](http://www.epa.gov/npdes)

<sup>54</sup> 80 FR 37053

now subject to federal CWA permitting requirements, can introduce new upfront costs, project delays and threats of litigation.” (146-NAM). The U.S. CoC suggests it includes “ditches, canals, and even land that is dry most of the year, as long as water runs over that land sometime on its way to interstate waters.” However, the EPA suggests the rule “focuses on streams, not ditches,” and “the rule limits protection to ditches that are constructed out of streams or function like streams and can carry pollution downstream. So ditches that are not constructed in streams and that flow only when it rains are not covered.”<sup>55</sup>

The rule has been stayed by the 6<sup>th</sup> Circuit Court of Appeals. President Trump has also issued an Executive Order on February 28, 2017, which asked the EPA and the Army Corp of Engineers to reconsider the WOTUS rule and the definition of “navigable waters”. (6-NFIB). The differences in perception between RFI respondents and the EPA suggest there is (at least) opportunity to clarify the definition of “waters of the U.S.” Many of the RFI respondents would like to see a narrower definition of “Waters of the U.S.” (6-NFIB, 146-NAM)

#### 5c.2. CAA: National Emissions Standards for Hazardous Air Pollutants (NESHAP)

The National Emissions Standards for Hazardous Air Pollutants limit emissions levels for specific pollutants from a variety of specific sources and manufacturing processes. For example, there is an emissions limit for arsenic in glass manufacturing furnaces.<sup>56</sup> The Air Permitting Forum provides a summary of how NESHAPs work:

*“The CAA Section 112 program covers the regulation of hazardous air pollutants (a defined list) for various source categories. Initially, these National Emission Standards for Hazardous Air Pollutants (NESHAPs) were established based on a review of currently employed air pollution control technology applied to existing and new sources (referred to as Maximum Achievable Control Technology, or MACT). Then, after eight years, the statute requires EPA to conduct residual risk and technology reviews. EPA assesses the risk remaining after application of MACT controls and determines if it is acceptable. If not acceptable, further controls must be applied. EPA is also required to evaluate if advances in control technologies have occurred since the MACT and to determine if their application to the source category is appropriate. (170-APF)*

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<sup>55</sup> EPA Clean Water Rule Fact Sheet

<sup>56</sup> <https://www.epa.gov/stationary-sources-air-pollution/inorganic-arsenic-emissions-glass-manufacturing-plants-national>

Because the standards are similar to another set of rules – the New Source Performance Standards, discussed below - a number of respondents have suggested there are opportunities to consolidate and rationalize their requirements. However, there are also a series of perceived “unnecessary burdens” specifically related to NESHAP.

A number of respondents expressed concern about the residual risk and technology reviews (RRTRs), as leading to unnecessary additional requirements with no (or limited) environmental benefit. In other words, once MACT controls were employed, the additional requirements were “overkill.” NAM provided the following illustrative example for a sandblasting operation:

*“For one manufacturer, this means having a dedicated employee climb on the roof of eight different manufacturing plants at the required interval (daily/weekly/monthly/quarterly) to do multiple 15-minute observations on each roof, and perform visual emissions of the on-site sandblasting booth at the required interval, only to document that zero visible emissions occurred at every observed location during every monitoring event. Since 2011, this manufacturer has made over 700 visual observations consuming over 1,000 man-hours to comply with this regulation, despite having not once observed a “visible emission” at any of the plants.” (146-NAM)*

Another example was provided for secondary aluminum production, illustrating how regulations that emerged from an RRTR lead to rules that did not reflect real world operating conditions. This rule required “hooding” for new “round top furnaces,” which were impractical because they were incongruent with the charging method for this type of furnace which requires an overhead crane and lifting of the lid (101-AA).

Another issue is related to the “once-in-always in” rule which means that a major source, subject to the MACT technology standard, remains subject to that standard even if *“the facility undertakes pollution prevention or installs control devices to reduce emissions below the major source applicability thresholds.”* (170-APF). That means a company is subject to a higher standard than is “justified” by their current emissions levels. Perversely, this creates a disincentive for companies to reduce emissions. (170-APF)

One particular source category – MACT for industrial and commercial boilers and process heaters - has received particular attention in recent literature, and in the RFI responses. The rulemaking for this source category has gone on for 20 years, and is apparently being revised based on a 2016 court decision, which is causing the EPA to consider additional “best performing boilers”.<sup>57</sup> The length and complexity of the rulemaking process has created uncertainty for manufacturers.<sup>58</sup> In addition, specific burdensome requirements were identified by some respondents, such as steel facilities:

*“The requirement to test/tune/test each burner of each applicable source is a burdensome exercise. At many steel making facilities there are multiple finishing lines with indirect heating furnaces that are comprised of hundreds of natural gas fired burners each below 5 MMBTU/hour. These units are considered cumulatively under the Boiler MACT and are therefore required to have annual tune-ups per 40 CFR. § 63.7515(d). The annual tune-ups require excessive line outages and man hours. The annual requirement for testing and tuning of the many small burners can range up to \$100,000 for a company with the time, equipment and proper skills to conduct the tuning. For natural gas sources with burner sizes less than a certain threshold, reducing the frequency of these tune-ups to every five years would significantly reduce the cost burden.” (92-AISI)*

The Clean Air Act defines emissions limits for specific types of stationary sources. These New Source Performance Standards (NSPS) are specific to 90 different industries/manufacturing processes. NSPS applies to “new, modified and reconstructed” facilities. As an example, there is an NSPS standard for VOCs for surface coating processes for large appliances.<sup>59</sup>

For NSPS, the specific regulatory burdens cited often were not the rules themselves, but the potential for overlap and redundancy with related rules, such as National Emissions Standards for Hazardous Air Pollutants (NESHAPS, discussed above). NAM and IECA specifically suggest there are opportunities to rationalize the NSPS and NESHAP requirements, reporting and recordkeeping (146-NAM, 89-IECA). Both sets of rules limit emissions from specific manufacturing processes, suggesting that there may be

<sup>57</sup> <https://www.epa.gov/boilers>, 146- NAM

<sup>58</sup> Paul R. Noe, Article “Smarter Regulation for the American Manufacturing Economy”, Oct. 25, 2016

<sup>59</sup> <https://www.epa.gov/stationary-sources-air-pollution/large-appliances-industrial-surface-coating-new-source-performance>



opportunities to integrate the two standards. NAM gives a specific example of the opportunity to rationalize 8 different regulations for different coatings processes (146-NAM).

More frequently mentioned were examples of enforcement reaching beyond explicit NSPS standards. (89-IECA, 92-AISI, 112-SMA). AISI gives the example of the EPA using enforcement actions to limit fugitive emissions of particulate matter in steel making facilities that are not explicitly delineated in the NSPS. (92-AISI).

#### 5c.3. CAA: New Source Review and Prevention of Significant Deterioration Permits (NSR and PSD)

The New Source Review (NSR) permitting program under the Clean Air Act was cited in many of the RFI responses as one of the most important opportunities to streamline permitting processes for manufacturers. An NSR “pre-construction” permit is required for new industrial facilities (and other new “major sources”) or for “major modifications” of existing facilities<sup>60</sup>. The objectives of the program are to protect air quality by limiting increases in emissions and by ensuring that “advances in pollution control technology occur” as part of industrial expansion<sup>61</sup>. The NSR program has different requirements depending on whether facilities are in “attainment” areas that are meeting National Ambient Air Quality Standards (NAAQS) for 6 specific “criteria” pollutants, or whether they are in non-attainment areas. Permits in attainment areas are known as Prevention of Significant Deterioration (or PSD) permits. The table below outlines the broad requirements for NSR and PSD permits:

| Nonattainment NSR                                                                                                                                                                                                                                          | PSD (attainment area)                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. The Lowest Achievable Emission Rate or LAER ( <i>“meaning that the plant must install state-of-the-art pollution controls in order to match or exceed the emission rate achieved by the lowest emitting similar facility in the country”</i> ) (48-RFF) | 1. Installation of the Best Available Control Technology or BACT (similar to LAER, but sometimes less stringent, and assessed on a case-by-case basis) (48-RFF) |

<sup>60</sup> [www.epa.gov/NSR](http://www.epa.gov/NSR), 48-RFF

<sup>61</sup> [www.epa.gov/NSR](http://www.epa.gov/NSR), 48-RFF

|                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. Emissions offsets (reductions) from other plants in the same area that yield a net air quality benefit for the region                                                                                                                                                                                                                                   | 2. An air impact analysis or modeling that demonstrates that the increase in emissions: 1) <i>“will not result in changes in ambient air quality that would cause the area to exceed NAAQS for any pollutant, and 2) even if projected emissions will not violate NAAQS, they will not result in an increase in ambient concentrations of any pollutant that exceeds the allowable PSD “increments” set by the CAA.”</i> |
| 3. Alternative Sites Analysis                                                                                                                                                                                                                                                                                                                              | 3. An additional impacts analysis (which “assesses the impacts of air, ground and water pollution on soils, vegetation, and visibility caused by any increase in emissions of any regulated pollutant” from the source) <sup>62</sup>                                                                                                                                                                                    |
| 4. Opportunities for public comment                                                                                                                                                                                                                                                                                                                        | 4. Opportunities for public comment                                                                                                                                                                                                                                                                                                                                                                                      |
| Sources: <a href="http://www.epa.gov/nsr">www.epa.gov/nsr</a> , 48-RFF, 92-AISI, 136-AFPM, EPA, Webinar Slides: <i>Revisions to the Prevention of Significant Deterioration (PSD) and Title V Greenhouse Gas (GHG) Permitting Regulations and Establishment of a GHG Significant Emission Rate (SER): Proposed Rule</i> , September 20, 2016 <sup>63</sup> |                                                                                                                                                                                                                                                                                                                                                                                                                          |

796

797 The NSR/PSD permitting processes are perceived by RFI respondents to be unnecessarily cumbersome  
798 and lengthy. The time required to obtain a permit, once an application is received, can range from 9 months  
799 to as much as 2-3 years (48-RFF, 170-APF). This duration does not include the months (or even years)  
800 required to prepare the application, nor does it include potential delays that can lengthen the process or  
801 make its timing uncertain, such as the need to revise air quality modeling when a NAAQS standard is  
802 changed, or the possibility of an appeal or review by the EPA of state decision to issue a permit (170-APF,  
803 10-PA, 89-IECA).

804

805 RFI respondents indicated the costs to prepare an application and construct air quality and dispersion  
806 models are significant, not to mention the costs of emissions offsets and what is sometimes perceived as

<sup>62</sup> [www.epa.gov/nsr](http://www.epa.gov/nsr)  
<sup>63</sup> 81 FR 68110

“over-investment” in pollution control equipment due to the conservative assumptions built into these models. (Both of these factors are discussed further below). The result is that manufacturers avoid making investments to modernize facilities, improve processes or increase quality for fear of triggering an NSR/PSD requirement. (146-NAM, 10-PA)

In addition to the goal of reducing turnaround times and costs, a number of specific issues and recommendations have been put forward:

- *Turnaround Time.* One obvious proposal is to enforce reasonable turnaround times. According to RFF, “under the CAA, EPA and other permitting agencies are required to either grant or deny an NSR permit within one year of receiving a permit application, but there is no practical way to enforce this deadline.” In addition to setting firm deadlines, other suggestions include:
  - Limiting challenges or appeals, including limiting the ability of the EPA to review or reject the decision of a state permitting authority. (89-IECA, 170-APF, 10-PA)
  - Allowing some construction activities to commence that do not generate emissions, prior to receiving a permit (146-NAM)
- *Aggregation.* There are also a set of rules regarding the “aggregation” of emissions (within a facility, over time within a facility, or across locations) that affect whether the need for a NSR/PSD permit process is triggered. A number of respondents made suggestions or encouraged rules that allow flexibility for sources to aggregate emissions and thus demonstrate that total emissions are not increasing sufficiently to trigger an NSR/PSD process. (In some cases this would involve clarifying rules or “solidifying” past reforms already proposed.) These recommendations include:
  - PALs - EPA could promote and facilitate “*Plant-Wide Applicability Limitations (basically emissions limits that apply facility-wide) through a permitting process, allowing such a facility to change, modify and upgrade equipment and operations and add new equipment without triggering major modification NSR review, provided the changes do not result in exceeding the established PAL emissions limits.*” (92-AISI quote, also 170-APF).
  - Units that are “upstream or downstream” from the unit being modified should not be considered as part of emissions increases that might trigger NSR (170-APF, 136-AFPM)

- Clarifying the rules around definition of a project, and whether separate activities can be grouped together into a project for purposes of triggering NSR/PSD (170-APF, 136-AFPM, 146-NAM)
- *Rules that Avoid Triggering NSR.* There were also recommendations around rules that would allow companies to avoid triggering NSR, such as:
  - Revisiting and expanding the definition of activities that are defined as “routine maintenance, repair and replacement”, which are exempted from NSR/PSD requirements. (92-AISI, 170-APF)
  - Using actual emission increases versus theoretical or maximum “potential to emit” in calculations (10-PA, 136-AFPM). Note that other respondents suggested this reform has already been made, suggesting the idea that these rules should be clarified. (136-AFPM, 48-RFF)
- *Modeling.* Numerous respondents identified the need to avoid delays and re-work in the application and air quality modeling process. (Note that a more general discussion of NAAQS and modeling is found in the section below.) Recommendations include:
  - Introducing guidance on modeling at the same time as NAAQS standards are revised, so there is clarity on modeling required as part of an NSR application. (92-AISI, 48-RFF)
  - “Grandfathering” NSR applications that were submitted, but not yet approved, prior to a change to NAAQS standards, so companies do not have to revise the applications to conform to the new standards. (92-AISI, 48-RFF)
- *BACT and LAER determinations.* Several respondents offered suggestions about how to improve the process of determining the required pollution control technology, which is perceived to be onerous and susceptible to delays:
  - PSD BACT determination should be based on proven, domestic technology that is in the same “industrial category” as the applicant and was in existence when the application was submitted (92-AISI, 10-PA) and should consider alternatives to the “top down” BACT analysis process. (170-APF)
- *Emissions Credits or Offsets.* There can be challenges in obtaining emissions credits in non-attainment areas, and when they are available they can be very expensive. In one example, a relatively small new facility in Houston (emitting more than 100 tpy of Volatile Organic Compounds

or NO<sub>2</sub>) might need to spend \$32-52M for emissions offsets. (48-RFF) Recommendations by respondents include:

- Relaxing the restrictions on buying offsets from outside the local areas where a new facility is being established. (48-RFF)
- Emission fees versus credits (which would require a statutory change) (48-RFF) As one respondent stated: *“We propose a narrow statutory reform that could address these issues while still obtaining most or perhaps even more of the environmental benefits of the current program: allow permit applicants to pay emissions fees in lieu of meeting the current offset requirements, and require the state or local environmental agency to use these fees to pay for or subsidize emissions reductions that the agency believes will do the most good in terms of reducing environmental risks.”* (48-RFF)

The other major permit required by the CAA (beyond NSR/PSD) is the Title V operating permit for major (and some minor) sources, which incorporates all of the federal and state air pollution control requirements in one place (170-APF). The operating permit must be renewed every 5 years.

Industry respondents suggested that it has become costly to obtain, maintain and renew operating permits. (170-APF). AISI reported *“varied timelines for completing the Title V review and approval process, depending on the state regulatory agency and EPA Regional Office, taking up to three years to receive the final permit and costs of several million dollars for each operating permit needed.”* (92-AISI). And according to the Air Permitting Forum, *“the cost of the program today is far more than was ever anticipated...given the enormous costs of the program, it is incumbent on the government to take whatever steps it can to streamline permitting and minimize costs”* (170-APF). The impression is that an attempt to consolidate requirements (in the Title V permit) actually has added another layer of bureaucracy.

In some cases, even though an NSR/PSD pre-construction permit has already been obtained, the Title V permit process provides another opportunity for NGOs or others to mount a legal challenge *“on the same grounds that have already been adjudicated.”* (170-APF) Moreover, *“Title V petitions often sit in a long queue at EPA, and then can end up back in court—duplicating costs for industry to defend its expansive and long-evaluated permits.”* (170-APF)

A related problem is the concern that the operating permit – which is intended to consolidate other requirements – is being used (e.g., by states) to add additional requirements or impede flexibility in meeting other requirements imposed by the CAA (e.g., such as using the permit language to limit the options for an appliance surface coating operation in meeting MACT standards for hazardous air pollutants (HAPs), which otherwise would be able to meet requirements by changing materials or adopting controls). (170-APF)

In addition to an overall desire to streamline the process, specific recommendations include: eliminating the ability of EPA or other stakeholders from “re-litigating” pre-construction NSR/PSD permit decisions during the Title V permitting process (170-APF); extending the term of the permit from 5 to 10 years (170-APF); and citing other requirements in the permit rather than recreating or summarizing those requirements in their entirety in the permit itself. (170-APF)

Historically, CAA has exempted Start-up, Shutdown and Malfunctions (SSM) periods from the emissions restrictions that apply under normal operating periods. However, in response to recent court decisions, the EPA has apparently reversed course and has proposed new rules (in 2016) to eliminate these exemptions and eliminate the “affirmative defense” provision for emergencies. Numerous industry respondents have urged that the SSM exemptions be restored (89-IECA, 170-APF, 92-AISI):

*“Unless EPA acts quickly, every manufacturing company in the country operating under a Title V air permit could be subjected to unnecessary citizen suits and potential civil penalties as they shut down and start-up their equipment to conduct maintenance activities and other planned and unplanned outages.”* (89-IECA)

It has also been suggested that other alternative approaches could be explored, such as developing a more “judicially sound affirmative defense concept” or “re-promulgating technology based emissions standards sufficient to cover emissions associated with SSM events.” (101-AA)

#### 5c.4. CWA: National Pollutant Discharge Elimination System (NPDES) Permits

The CWA requires a permit – through the EPA’s National Pollutant Discharge Elimination System – to discharge pollutants from a “point source” into a “water of the United States.” *“The permit will contain limits on what you can discharge, monitoring and reporting requirements, and other provisions to ensure that the*

*discharge does not hurt water quality or people's health.*<sup>64</sup> An NPDES Storm-water program also requires a permit for some storm-water discharges, which are not considered point sources.<sup>65</sup> Also under the CWA, a section 404 permit may be required for the discharge of dredge or fill material into “waters of the US”. Section 404 is managed by the EPA and US Army Corps of Engineers.

The main concern expressed by RFI respondents was the complexity these permitting processes, and the time required to obtain a permit. According to AISI *“The 404 permitting process is currently one of the most ill-defined processes for a regulated party to understand and thus to predict permit timelines.”* (92-AISI). Respondents claim Section 404 permits can take 1-4 years to obtain (and later in the document claim 2-6 years), and NPDES permits require 6 months or more. (92-AISI). In reference to wetlands (Section 404) permitting, SMA stated that *“USACE [US Army Corps of Engineers] permitting processes are slow, antiquated and expensive.”* (112-SMA). And regarding NPDES, the Aluminum Association’s assessment is that the *“antiquated permitting timeline embedded in these regulations costs business money and lost opportunities for growth.”* (101-AA)

Some of this long permitting cycle is driven by the complexity of the law and these programs, involving permits from industrial discharges from point sources, often based on effluent guidelines for specific industrial processes (which are sometimes complicated by Total Maximum Daily Load limits on the amount of *“pollutant a waterbody can receive”*), a separate permit process for discharges that go into publicly owned treatment works (POTWs), separate permits for storm water, separate Section 404 permits for wetlands, a set of requirements for cooling water intake water, and significant operational proscriptions and recordkeeping/reporting.<sup>66</sup>

The recommendations generally revolve around streamlining the process, eliminating duplicative requirements, making the steps to obtain a permit more defined (with fewer open-ended steps), and shortening the process timeline. (92-AISI, 101-AA, 76-Boeing)

#### 5c.5. CAA: Greenhouse Gas Requirements

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<sup>64</sup> [www.epa.gov/npdes](http://www.epa.gov/npdes)

<sup>65</sup> [www.epa.gov/npdes](http://www.epa.gov/npdes)

<sup>66</sup> [www.epa.gov/npdes](http://www.epa.gov/npdes), 92-AISI; 112-SMA; 136-AFPM; 101-AA

Greenhouse Gas Emissions (GHGs) are now regulated under the CAA, using PSD and Title V permitting processes. The objective was to introduce “*GHG emissions thresholds that define when permits under these permitting programs were required*” for new or modified sources.<sup>67</sup> Litigation in 2014/15 has caused a revision of the rules, which is still in progress (*Utility Air Regulatory Group v. EPA*, *Coalition for Responsible Regulation v. EPA*). The primary result of the decision was that the EPA “*may not treat GHGs as an air pollutant for the specific purpose of determining whether a source is required to obtain a PSD or title V permit.*”<sup>68</sup> In other words, a “*BACT analysis for GHGs*” is only required in cases “*where another air pollutant triggers a review*” and the requirement to obtain a PSD or Title V permit. (136-AFPM). A revised rule has been proposed, and final comments were due in December 2016.

Nevertheless, for major sources that require Title V and PSD permits for another pollutant, EPA can apply BACT requirements to GHGs above a specific threshold, which has been proposed at 75,000 tons per year (tpy) CO<sub>2</sub>e Significant Emission Rate (SER). The court decisions referred to above also require a justification for this threshold level. There is concern among a number of RFI respondents that this threshold level of GHG emissions is too low, and that the benefit in terms of GHG emissions would not justify the additional regulatory burden. (89-IECA, 136-AFPM). We therefore recommend the EPA prioritize an expedited and judicious review of SER thresholds for GHGs.

#### 5c.6. CAA: National Ambient Air Quality Standards (NAAQS)

The EPA establishes National Ambient Air Quality Standards for six “criteria” air pollutants (carbon monoxide, ozone, lead, nitrogen dioxide, particulate matter, and sulfur dioxide). Regions are designated as “attainment” areas (which meet the NAAQS standards), non-attainment regions, or unclassified. Non-attainment regions are considerably more restricted in allowable emissions, thus limiting the potential for new manufacturing plants and plant expansions. “Attainment” is perceived to be increasingly challenging as NAAQS standards are continually ratcheted downward, and many respondents indicated the levels are now approaching “background levels.” (146-NAM, 112-SMA) The more restrictive standard makes it particularly

<sup>67</sup> webinar slides on “Revisions to the Prevention of Significant Deterioration (PSD) and Title V Greenhouse Gas (GHG) Permitting Regulations and Establishment of a GHG Significant Emission Rate (SER): Proposed Rule”, Sept. 20, 2016; <https://www.epa.gov/sites/production/files/2016-10/documents/20160920-nsr-webinar-slides.pdf>

<sup>68</sup> webinar slides on “Revisions to the Prevention of Significant Deterioration (PSD) and Title V Greenhouse Gas (GHG) Permitting Regulations and Establishment of a GHG Significant Emission Rate (SER): Proposed Rule”, Sept. 20, 2016; <https://www.epa.gov/sites/production/files/2016-10/documents/20160920-nsr-webinar-slides.pdf>



difficult to obtain a permit under the NSR/PSD programs, as it becomes difficult to demonstrate that emissions will not contribute to a violation of the standard.

Because of this narrow margin, numerous respondents identified the need for EPA to improve air quality and dispersion models. A good summary of the situation was offered by the Air Permitting Forum:

*In conducting an analysis for the PSD program, facilities must use EPA-approved models to demonstrate that a project will not cause a violation of a NAAQS standard. The models' overly conservative algorithms and assumptions, however, can create a modeling result that rarely represents and often significantly overestimates monitored concentrations around the facility. Reliance on modeling that over-predicts ambient concentrations can result in additional unwarranted costs by causing facilities to install beyond-BACT pollution control equipment, even though the assumptions used in the models and the predicted concentrations are not representative of real-world conditions. (170-APF)*

Some of the specific suggestions to improve the approach involved re-examining assumptions about background concentration levels, the treatment of fugitive emissions, use of actual emissions rather than theoretical or maximum operating rates, employing probabilistic models, and reconsidering inappropriate "ambient air receptor" locations where individuals will not generally be exposed to emissions. (89-IECA, 92-AISI, 170-APF, 112-SMA, 136-AFPM)

NAAQS revisions are required to be updated every five years, but several respondents suggested that these revisions should be extended to 10 years to allow states to implement the standards; this would also make it easier for the EPA to release updated modeling guidelines at the same time as the new standard (10-PA)

The current NAAQS standard for ozone is considered by some observers as too difficult to meet, shifting numerous regions into a non-attainment designation, and severely restricting the ability for manufacturing companies to establish new, or expand existing facilities in those regions. (136-AFPM, 112-SMA, 89-IECA)

1011 According to NAM *“the 2015 ozone regulation could be one of the most expensive regulations ever issued*  
1012 *by the U.S. government.”* (146-NAM)<sup>69</sup>

1013  
1014 The 2015 ozone regulation established a standard of 70 parts per billion (ppb). The previous standard,  
1015 established in 2008 of 75 ppb, was never fully implemented (89-IECA, 136-AFPM). And at 70 ppb,  
1016 observers claim the level is approaching “background” levels of ozone (48-RFF). The feedback from  
1017 industry is that the pace at which the standard has been tightened has been too rapid, and is further  
1018 complicated by measurement and (again) air quality modeling issues – in particular accounting for ozone  
1019 transported from international sources (112-SMA,107-COC). As noted in the RFF response:

1020  
1021 *Recent research has found that stratospheric intrusions and long-range transport—particularly*  
1022 *in western states—have resulted in daily maximum eight-hour ozone levels of 70 ppb or more. With*  
1023 *the ozone NAAQS at or below background, sources will find it impossible to show that they will not*  
1024 *“contribute to” a violation of the standard.* (48-RFF)

1025  
1026 Some observers indicated that the standard is too stringent or the implementation should be delayed.<sup>70</sup>  
1027 Others have recommended that changing NAAQS revisions from every five years to every 10, would allow  
1028 more time to meet the previous standard. (107-COC, 136-AFPM) In addition, the U.S. Chamber of  
1029 Commerce (CoC) notes that these “five-year deadlines are regularly exceeded by the EPA and inevitably  
1030 result in ‘sue-and-settle’ agreements”. Five-year review cycles result in over regulation and constant  
1031 changes requiring capital outlays from the private sector. The EPA should pursue required actions to  
1032 update the NAAQS review schedule to reflect a 10-year cycle. This would allow for complete realization of  
1033 environmental improvements, and would bring greater certainty to regulated operators.

1034  
1035 Another issue is to re-examine and clarify how to account for international and long-range transport of  
1036 ozone, and exceptional events. The EPA has a policy which would allow it to *“disregard exceedances of a*  
1037 *NAAQS caused by certain types of exceptional events,”* such as stratospheric intrusions. However, it was

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<sup>69</sup> A NAM-NERA 2014 report assessed the impact of a more stringent 60ppb standard that was contemplated at the time, and the analysis suggested the economic impact would be enormous: “...the potential emissions control costs would reduce U.S. Gross Domestic Product (GDP) by \$270 billion per year on average over the period from 2017 through 2040... The potential labor market impacts represent an average annual loss of 2.9 million job-equivalents.” (NERA, “Assessing Economic Impacts of a Stricter National Ambient Air Quality Standard for Ozone”, NAM, July 2014) In contrast, the EPA estimated costs of \$560M for what appears to be the final rule of 70ppb. (OMB, “2016 Draft Report”)

<sup>70</sup> 146-NAM, Business Roundtable, letter to National Economic Council re. regulations of concern, February 22, 2017

suggested that in practice it is difficult to obtain EPA “recognition” of exceptional events in an NSR application. (48-RFF). In light of this phenomenon, where meteorological conditions play a role in transporting extra-jurisdictional emissions, the EPA should exclude those emissions from regulatory consideration, classifying them as “exceptional events”. The EPA should employ all tools available to discount for “background” conditions and allow maximum degree of flexibility afforded by statute.

#### 5c.7. Resource Conservation and Recovery Act (RCRA)

The RCRA is a set of laws, regulations and policies that govern management and cleanup of solid, liquid, and gaseous hazardous waste.<sup>71</sup> Manufacturers are impacted because of the generation of waste streams in factories. An issue identified by several respondents is the perceived inappropriate classification of certain waste streams as hazardous, which impose burdensome additional requirements, and have the perverse effect of discouraging recycling, reuse or reclamation (146-NAM). For example, AISI has proposed that baghouse dust from electric arc furnaces (EAFs) be delisted as hazardous, which would open up additional recycling or reuse opportunities (without always employing an RCRA-permitted recycling operator). SMA similarly suggested by-products from EAFs are sometimes classified as hazardous, resulting in more complex and burdensome management requirements, which again undermine the goal of recycling. (112-SMA). The rule has added a restrictive criterion for “legitimacy” which results in unnecessary treatment and disposal of material that could be reused or recycled for other purposes. We therefore recommend the EPA update the rule [80 Fed. Reg. 1693-1814 (Jan. 13,2015), revising 40 CFR. Parts 260 & 261] to allow for more beneficial uses of substances where reuse or recycling can be justified by industry. Additionally, an aggressive approach to delisting waste, where appropriate, as “hazardous” would reduce regulatory burden. (76-Boeing)

Also, the EPA recently published the Hazardous Waste Generators Improvement Rule<sup>72</sup>. According to IECA it “causes waste generators who violate even one ‘Condition for Exemption’ from permitting to be treated as [full-fledged] waste treatment, storage, and disposal facilities requiring RCRA permits. Violation of a single minor condition can therefore mean that an otherwise exempt facility must obtain a RCRA permit and can be cited for violations of numerous regulations and permit conditions” (136-AFPM) or be subject to

<sup>71</sup> <https://www.epa.gov/rcra>

<sup>72</sup> 81 FR 85732

more onerous regulations. (89-IECA). The rule should be revised to allow some leeway on conditions of exemption and associated violations.

#### 5c.8. Risk Management Programs

In response to the explosion of a chemical facility in West Texas, the Obama Administration issued Executive Order 13650, entitled “Improving Chemical Facility Safety and Security,” which directed the federal government to “improve operational coordination with state and local partners, improve federal agency coordination and information sharing, modernize policies, regulations and standards, and work with stakeholders to identify best practices in chemical facility safety and security” (136-AFPM). Using this EO as a basis, EPA revised its Risk Management Programs regulations (40 CFR, Part 68, finalized in 2017), which numerous respondents suggested would add unnecessary or unreasonable additional burden.

Several issues were raised. First, there is significant concern about duplication and conflicting requirements with OSHA Process Safety Management standard (A136-AFPM, 43-Mosaic, 133-PIA). In addition, several elements of the new requirements were perceived as unnecessary or inflexible. One such area is the requirement for third party audits that would be required in certain circumstances (such as chemical release or instance of non-compliance) (136-AFPM, 109-Valero). One respondent suggested appropriately trained internal staff could perform audits, and also suggested the qualifications for third parties outlined in the regulations were too restrictive (158-CKRC). An additional requirement highlighted was the need for a “resource-intensive inherently safer technology analysis” that according to one respondent “provides little value after a facility is already built” (136-AFPM), and another states will “increase compliance costs without improving safety.” (109-Valero). Finally, several respondents expressed concern about reporting requirements that would release sensitive information that could be used for lawsuits or potentially even terrorist attacks (146-NAM, 109-Valero, 136-AFPM). Going further, respondents have pointed out that the West Texas facility explosion – which instigated the revisions – is now believed to be caused by arson, and one respondent claims the new rules do not even apply to the facility that exploded (109-Valero, 136-AFPM)

Legal action has been taken to force reconsideration of the rules, and the EPA under the new Administration has agreed to delay the rule’s effective date to allow for this (136-AFPM).

1097 5c.9. Toxic Substance and Control Act

1098 The Toxic Substances Control Act (TSCA) of 1976 mandated the EPA to protect the public from  
1099 "unreasonable risk of injury to health or the environment" by regulating the manufacture and sale of  
1100 chemicals. TSCA mandates which types of chemicals could and could not be used in actual use and  
1101 production. For example, the use of chlorofluorocarbons in manufacturing is now strictly prohibited in all  
1102 manufacturing processes in the United States, even if no chlorofluorocarbons are released into the  
1103 atmosphere as a result. The types of chemicals regulated by the act fall into existing (already EPA-TSCA  
1104 approved) and new, which is an important distinction as the act regulates each category differently. For  
1105 new chemicals, manufacturers must submit premanufacturing notification to EPA prior to manufacturing or  
1106 importing new chemicals for commerce. Exceptions include substances used only in small quantities for  
1107 research and development under Section 5(h)(3), in areas such as foods, food additives, drugs, cosmetics  
1108 or devices (regulated under the Federal Food, Drug, and Cosmetic Act) and for pesticides (regulated by the  
1109 Federal Insecticide, Fungicide, and Rodenticide Act).

1110  
1111 The most common issue with TSCA expressed by the respondents was with the restrictions imposed on  
1112 manufacturing and use of chemicals, such as such as Trichloroethylene, Asbestos, and Medium and Long-  
1113 Chain Chlorinated Paraffins (37-ILMA, 39-IPC, 51-NSSGA, 56-CPA, 101-AA, 115-HSIA, 116-NAFO, 141-  
1114 ACC, 151-PESA, 155-PMPA). According these 10 RFI responses, these TSCA restrictions drastically and  
1115 unnecessarily negatively impacts profit, productivity, competition and jobs. For example, 101-AA expressed  
1116 a concern with the data TSCA used as a basis to restrict trichloroethylene (TCE) use. EPA's 2011 IRIS  
1117 assessment for trichloroethylene (TCE) reestablished cancer potency based on data that National  
1118 Research Council and California's Office of Environmental Health Hazard Assessment (OEHHA) both  
1119 dismissed and 11 EPA scientists expressed low confidence in. Despite the concerns with the data, EPA  
1120 has made no attempt to update or correct its assessment and associated restrictions.

1121  
1122 5c.10. Improve Tracking of Workforce Injuries and Illnesses  
1123 In May 2016, OSHA published its final rule to "Improve Tracking of Workplace Injuries and Illnesses"<sup>73</sup>.  
1124 However, manufacturers are concerned that this rule requires that companies submit electronic records of  
1125 workplace injuries and illnesses, which OSHA is planning to post on a public website. (92-AISI, 146-NAM,  
1126 107-COC). RFI respondents have voiced two objections to making the data publicly available: 1) the

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<sup>73</sup> 81 FR 29623

information may be used by union organizing campaigns, or as the basis of litigation on safety issues; 2) privacy concerns exist, as there may be identifying information included in the reporting that could expose sensitive, proprietary information. (92-AISI, 146-NAM, 107-COC).

Also, there are requirements for establishing a reasonable system for workers to report injury or illness, along with provisions that prevent employers from retaliating against whistleblowers or in other ways discouraging injury or illness reporting. Guidance issued on how to comply with the rules included language that suggested some safety performance incentives and drug testing programs might be construed as in violation of the rule, as they might deter reporting (to improve safety performance measures or to avoid post-accident drug testing) (107-COC; 92-AISI; 39-IPC). Respondents would like to see a reconsideration of the plan to post safety data online, and to clarify the guidance so that it does not undermine safety incentive and drug testing programs.

#### 5c.11. Endangered Species Act (ESA)

Specific concerns related to the Endangered Species Act (ESA) fall primarily into three categories. First, federal agencies issuing permits must consult with the U.S. Fish and Wildlife Service when construction may affect an endangered species; this consultation adds considerably to permit time and complexity. (51-NSSGA, 84-Ameren, 114-AGC, 136-AFPM). Due to high volumes, ESA rules have become “unreasonable,” such as the 2016 Critical Habitat Designations. (86-IPAA, 114-AGC, 144-AFPA, 146-NAM, 152-AWC). Finally, opposition groups use ESA to block or delay permits (75-SLMA, 107-COC, 126-API).

#### 5c.12. Conflict Minerals

Section 1502 of the Dodd-Frank Act<sup>74</sup> mandates that the U.S. Securities and Exchange Commission (SEC) create rules<sup>75</sup> that require public companies that use conflict minerals (tantalum, tin, gold or tungsten) in the manufacture of their products to “*undertake ‘due diligence’ on the source and chain of custody of its conflict minerals and file a Conflict Minerals Report*” and publicly disclose this information.<sup>76</sup> The concern is that the mineral may have come from or near the Democratic Republic of the Congo and its use therefore is

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<sup>74</sup> Dodd-Frank Wall Street Reform and Consumer Protection Act

<sup>75</sup> 17 CFR 240, 249

<sup>76</sup> SEC fact sheet, <https://www.sec.gov/opa/Article/2012-2012-163htm---related-materials.html>

contributing to a humanitarian crisis. A significant issue is that the due diligence requirement gets pushed back on to suppliers, which are often small to medium sized privately-owned manufacturers who cannot easily comply with this burden. (53-ACMA, 120-NTMA/PMA, 137-MEMA, 146-NAM) One respondent claims that both the Department of Commerce and the SEC stated they lacked the expertise in this type of back-to-the-mine-of-origin investigation, and given this, asks how small firms can be asked to do this. (120-NTMA/PMA) According to NAM, *“The SEC estimates that it will take the average manufacturer 480 hours annually to comply with this regulation.”*<sup>77</sup> Another association claimed, *“a large Tier 1 supplier estimated that their expenditures have totaled about \$3 million since the annual reporting requirements took effect. These costs include tracking the supply chains and processes of over 7,000 lower tier suppliers, evaluating the minerals tracking efforts of all suppliers, and categorizing the likelihood that a supplier’s products contain conflict minerals. Additional costs are incurred because all findings from the company’s suppliers must be manually entered into a database and categorized so that the information provided may be utilized by the Tier 1 supplier in preparing filings.”*(137-MEMA) Many respondents suggested that the rule be suspended (including 14-Chromaflo, 39-IPC, 53-ACMA, 71-Whirlpool, 107-COC, 120-NTMA/PMA, 137-MEMA; 146-NAM)

A second SEC issue was the CEO pay ratio disclosure provision required by Section 953(b) of the Dodd-Frank Act. This provision calls for public companies to disclose the ratio of employees’ median pay to the compensation of a company’s chief executive officer. The SEC finalized a rule for this provision in August 2015, and it becomes effective in 2018. NAM notes that this ratio is a “false and overly simplistic” metric of company compensation practices and it is burdensome due to the costs associated with calculating median pay. (146-NAM). The U.S. Chamber echoes those concerns and notes that some municipalities are “enacting a new tax based upon this ratio.” (107-COC). NAM asks that the SEC go beyond examining unanticipated compliance challenges, which it has done this year with a public comment period, and that SEC reconsider the rule entirely.

### 5c.13. National Environmental Policy Act (NEPA)

The National Environmental Policy Act (NEPA) is an environmental law that promotes the enhancement of the environment and established the President's Council on Environmental Quality (CEQ). The purpose of NEPA is to ensure that environmental factors are weighted equally when compared to other factors in the

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<sup>77</sup> NAM, “Holding US Back”

decision making process undertaken by federal agencies and to establish a national environmental policy. It requires all major projects with a federal nexus to submit a comprehensive review of their potential environmental impacts prior to construction. *“It is often the largest, costliest, most time-consuming regulatory hurdle that project sponsors, developers, construction managers and engineers face before they can build”* (146-NAM). Pursuant to NEPA, 42 USC, 4321, a public disclosure process is required to determine the least environmentally damaging practicable alternative and direct, indirect, and cumulative impacts analysis on a wide range of issues. *“This process can take 4 years even if a full Environmental Impact Analysis (CWA) is not required”* (43-Masaic).

The respondents discussed several negative impacts (e.g.; increased costs, and significant manufacturing and constructions delay) in agency regulations and processes resulting from the agencies complying with NEPA requirements (10-PCBI, 42-Novelis, 43-Mosaic, 46-ATT, 71-Whirlpool, 83-TM, 86-IPAA, 96-NMA, 101-AA, 114-AGCA, 115-HSIA, 125-BP, 136-AFPM, 146-NAM, 159-VI, 172-VI). The most frequently NEPA burden mentioned was associated with EPA. For example, *“significant costs and delays occur when EPA’s involvement in CAA review triggers a full Federal regulatory review under NEPA”* (159-VI). If such a “cross cutting” (overlapping) Federal review is triggered, then several levels of Federal review are required, including:

- a Cultural Resources Survey, as required by Section 106 of the National Historic Preservation Act (NHPA) of 1966;
- an Essential Fish Habitat (EFH) Assessment under the Magnuson-Stevens Fishery Conservation and Management Act, which is conducted by the National Oceanic and Atmospheric Administration (NOAA) National Marine Fisheries Service (NMFS); and
- Implementation of protections for endangered species or species of concern (e.g., Whooping Crane) by the US Fish and Wildlife Service (USFWS)

5c.14. Regional Haze Requirements

5c.15. Crystalline Silica Standard<sup>78</sup>

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<sup>78</sup> 81 FR 162885



In 2016, an OSHA rule was finalized which cut in half the permissible exposure to crystalline silica (for general industry and maritime) from 100 to 50 micrograms per cubic meter<sup>79</sup>. Silica can be found in a number of manufacturing operations, including foundries, glass making, paint manufacturing, porcelain manufacturing, and brick manufacturing. (107-COC). Compliance is required within 2 years after the effective date (2018). According to NAM the rule requires “*extensive and costly engineering controls...exposure monitoring, medical surveillance, work area restrictions, clean rooms and recordkeeping.*” (146-NAM).

Industry respondents suggest the standard is simply too stringent and will be difficult, costly or impossible with which to comply. Respondents claim the standard “*could force manufacturers to shut their doors*” or “*could potentially cause several types of manufacturing to leave the United States.*” (146-NAM, 107-COC). The U.S. CoC indicates that the previous standard was highly effective, reducing deaths from exposure to silica by over 93% since 1968, and further indicates the standard is being challenged in court (to determine if OSHA demonstrated “significant risk,” and “whether it is technologically and economically feasible” – a “statutory requirement for an OSHA standard).” (107-COC). Respondents have suggested that the rule should be rescinded or reviewed (presumably with a less stringent standard), and should focus on ensuring compliance with the previous standard.<sup>80</sup>

#### 5c.16. Overtime Rule

The new overtime rule (DOL) raises the salary level required for exemption from overtime pay of salaried white collar employees from \$23,660 to \$47,476<sup>81</sup>. A number of respondents suggested the salary level for this exemption was too high, that the rule exceeded statutory authority, and that the automatic escalation of this salary threshold over time would be too rapid. (146-NAM, 6-NFIB, 39-IPC, 107-COC, 120-NTMA/PMA). The rule has been stayed by the courts, and respondents suggest it should be reconsidered.

#### 5c.17. Comprehensive Environmental Response, Compensation, and Liability Act

The Comprehensive Environmental Response, Compensation, and Liability Act’s (CERCLA) major emphasis is on the cleanup of inactive hazardous waste sites and the liability for cleanup costs on arrangers and transporters of hazardous substances and on current and former owners of facilities where

<sup>79</sup> 146-NAM, 107-COC, Am. Forest, “Smarter Regulation”

<sup>80</sup> 146-NAM, 107-CoC, NFIB, Problem Regulations, January 24, 2017

<sup>81</sup> <https://www.dol.gov/whd/overtime/final2016/>

hazardous substances were disposed. CERCLA gives the President authority to clean up these sites under requirements generically referred to as “removal” or “remedial” provisions. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) outlines CERCLA’s implementing regulations. Agencies must follow the procedures and standards detailed in the NCP when remediating these sites.

RFI respondents refer to CERCLA as extremely expensive and duplicative with other regulations (84-Ameren, 92-AISI, 96-NMA, 101-AA, 110-Freeport, 111-GAC, 131-NMMA, 159-VI, 160-TCC). 160-TCC says “*under this policy, EPA routinely requires cooperating private parties to pay for duplicative and unnecessary expenses that the Agency incurs—in addition to the substantial expenditures the private parties are already undertaking in order to remediate the site. EPA’s duplicative oversight activities not only increase costs, but also impede the pace of remediation by adding layers of unnecessary review. In 2015, EPA billed private parties \$106.4 million for agency oversight—a substantial amount of overhead costs and resources that are better spent directly on cleanup activities.*”<sup>82</sup>

#### 5c.18. Spill Prevention, Control, and Countermeasures

EPA, within the CWA, requires non-exempt facilities to prepare Spill Prevention, Control and Countermeasures (SPCC) plans to prevent the discharge of oil from non-transportation related onshore and offshore facilities into U.S. navigable waters or adjoining shorelines. The SPCC rule applies to owners or operators of non-transportation related facilities who drill, produce, store, process, refine, transfer, distribute, use or consume oil or oil products that meet at least one of the capacity thresholds and have the potential to discharge oil to U.S. navigable waters or adjoining shorelines.

The biggest concern with SPCC is the overlap with other federal regulations. Most frequently is a reference to SPCC overlapping with Stormwater Pollution Prevention Plan (SWPPP) which is duplicative effort that adds costs to the manufacturer and delay construction and operations (37-ILMA, 76-Boeing, 101-AA, 106-AGCA, 107-CoC, 114-AGCA, 127-PCA). According to 114-AGCA, “*construction site operators are required to develop plans for preventing, containing, and cleaning up oil spills under the NPDES and SCPP regulations. If a construction site operator has a SWPPP that addresses oil storage and spill control, containment and cleanup measures, then EPA should allow the jobsite SWPPP to also satisfy the agency’s*

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<sup>82</sup> U.S. Environmental Protection Agency, “Superfund Remedial Annual Accomplishments,” <https://www.epa.gov/superfund/superfund-remedial-annual-accomplishments>

SPCC requirements. Otherwise, this is double regulation – and each plan carries significant costs for the contractor to develop. The list of overlapping requirements includes documentation, management certification, site maps and diagrams, inspection and maintenance, recordkeeping, training, designated employees, notification procedures and response obligations. The U.S. Coast Guard also is involved in spill plans if the project is on/over water, which add further delays.”

5c.19. EEO-1 form.

The Equal Employment Opportunity Commission (EEOC) recently revised the reporting requirements so that beginning in 2018 employers will be required to submit more comprehensive and detailed information that will be used to enforce prohibitions against employment discrimination and address discriminatory pay practices between women and men and among different ethnicities and races. Employers with 100 or more employees (both private industry and federal contractors) will be required to submit data on employees' W-2 earnings and hours worked by ethnicity, race, and sex, sorted into 10 job categories. Responding organizations are concerned with the additional time and resources that they will need to spend on this form and estimate that the number of reported entries will increase from less than 200 data points to over 3,000. (107-COC, 137-MEMA, 119-AGC, 77-CIRT, 66-ARTBA,37-ILMA) Furthermore, responding organizations do not believe that the expanded data collection will provide useful information needed to enforce discriminatory pay practices. (107-COC, 137-MEMA, 119-AGC, 77-CIRT, 66-ARTBA,37-ILMA) Additionally, the additional reporting may put a company at risk of publicly disclosing employees' private information and/or proprietary company information. (146-NAM, 66-ARTBA, 37-ILMA)

5c.20. Food Safety Modernization Act

Over the last several years, the Food and Drug Administration (FDA), part of the Department of Health and Human Services (HHS), has issued several regulations to implement the Food Safety Modernization Act (FSMA). Some portions of the new regulations are complex, and a misinterpretation could cause potentially negative consequences for a company. One such regulation, Mitigation Strategies to Protect Food Against Intentional Adulteration (IA rule), is aimed at preventing intentional adulteration of food from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply.<sup>83</sup> The regulation imposes significant new requirements on manufacturers of human food, including maintaining certain records. FDA should delay the compliance dates for the IA rule until FDA has revised

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<sup>83</sup> 81 FR 34165

the regulation to provide for more flexibility and greater focus on risk-based methods of preventing intentional adulteration of the food system. (98-IDFA)

As manufacturing and agricultural processing continually evolves, the FDA should ensure that regulatory requirements are flexible and able to adapt to science and innovation. Many agriculture processing companies sell secondary products (e.g., germ, feed, meal) from facilities which were not designed to handle these ingredients to the same standards as ingredients intended for human consumption. In the new FSMA foundational regulations, “manufacturing/processing” has been broadly defined around different activities conducted on food. The “farm” has a narrower definition. As a result, numerous activities that farms normally use to prepare a food crop for trade as Raw Agricultural Commodities (RAC) can be considered activities that transform the crop into a “processed food.” A farm conducting these activities could be considered a manufacturer/processor and would be subject to food facility registration and to new requirements for “good manufacturing practices” and preventive controls. Current regulations will require some manufacturers to update facilities or adjust business practices to comply with good manufacturing requirements. There is a concern that such requirements are unnecessary and will result in lost jobs and lost opportunities for manufacturers. (146-NAM, 122-AHPA)

Additionally, the FSMA requires sellers (farmers and food processors) to obtain from their customers (downstream food processors and distributors) certain “written assurances” on an annual basis. With these written assurances in place, the sellers are provided a certain amount of regulatory relief – relief which in many cases is essential to the continued existence of their business, since according to respondents it is nearly impossible (not just inefficient or uneconomical) for the firm otherwise to comply with the applicable regulations. An analysis by the Grocery Manufacturers Association (GMA) determined that just the provisions in 21 CFR § 117.136 would require individual firms to obtain thousands or even millions of assurances every year. Therefore, the FDA should remove these unnecessary and burdensome provisions from the regulations. (70-GMA)

Commenters raised other FDA concerns as well, such as the Nutrition Labelling Standards. To provide consumers with clearer nutritional content information for food, based on updated nutrition research and public health information, the FDA issued a regulation in May 2016<sup>84</sup> that would require changes to the

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<sup>84</sup> 81 FR 33741

Nutrition Labeling, 21 CFR. §101.9 and Reference Amounts Customarily Consumed Per Eating Occasion (serving size) regulations, 21 CFR. § 101.12. These changes represent the first major update to the Nutrition Facts label in over 20 years and result in a massive overhaul to the food package label and information provided to consumers. FDA provided food manufacturers until July 26, 2018 to make this change even though FDA's own Regulatory Impact Analysis for this change estimated the cost to industry to comply in two years would be \$4.6 billion, whereas the cost to comply in four years would be \$2.8 billion. In other words, just extending the compliance deadline from two to four years saves \$1.8 billion. The challenge of compliance is compounded because FDA has yet to issue final guidance on the types of dietary fiber it considers to meet the new definition, 21 CFR §101.9(c)(6)(i), and information on calculating added sugars for some types of food, 21 CFR § 101.9(c)(6)(iii), which must be listed in the new label format. Additionally, the USDA is mandated by law to issue a regulation requiring the disclosure of the content of genetically modified ingredients in all foods by July 29, 2018, three days after the compliance deadline for the Nutrition Facts updates. FDA should extend the compliance date for this labeling update until May 2021 to ease the regulatory burden. Additional compliance time would allow companies to coordinate labeling updates, provide consumers with clear information to help them make healthy choices and avoid wasteful spending on duplicate relabeling schemes that would be required during the next four years. Additionally, USDA and FDA should work together on timing of compliance with these required changes so that manufacturers will only be required to make one label change. (98-IDFA, 146-NAM, 122-AHPA, 70-GMA, 74-Knouse). Other regulatory redundancies should also be eliminated between FDA, USDA, EPA, and other federal agencies. (53-ACMA, 74-Knouse, 64-TFI, 85-NOPA)

## **6. Overall Approach to Regulatory Reform and Streamlining of Permitting Processes**

### *6a. Introduction*

Many regulatory reform initiatives have been undertaken, as discussed in Section 4, yet regulatory burdens continue to grow. In this section, we examine what the literature and RFI responses say about how or why reforms have failed, and identify potential solutions and recommendations for reducing regulatory burdens. First, we tackle reforms for *new* rules, which address how the rulemaking process can be improved to design rules that minimize the burden of achieving a desired outcome. Then we address reforms for *existing* rules, which aim to reduce the current compliance burden (without impacting benefits).

A key theme throughout this section is that while reforms are difficult to enact, they are even more difficult to carry out. In addition, over the years, copious effort has been spent on analysis and suggestions for federal regulatory reform by think tanks, industry associations, as well as government agencies because regulations represent a debilitating national problem, yet the burden for manufacturers continues to grow. Through this process it became clear that at the manufacturing plant level, there are significant opportunities for burden reduction. Regulators and manufacturers working together can eliminate unnecessary regulatory burdens. Numerous examples were given of impractical, unrealistic, or onerous requirements and of processes that make permitting unnecessarily complex and time consuming. These unnecessary burdens can be eliminated if regulators work with industry to apply commonsense and practicality to regulations and re-form requirements to reflect real world operating conditions.

*6b. New Rules: Improving the Rulemaking Process*

Many of the reforms attempted in the past focus on creating effective rules. And yet, Section 4 illustrates that the same reforms were attempted many times, making it clear that they were not all successful. In part, this is because, for agencies, complying with reform attempts is challenging and requires significant resources. Because of this difficulty, Executive Orders and Presidential Memoranda are not sufficient to ensure compliance; loopholes in EOs and legislation may be exploited. Therefore, in order to make headway, rigorous reviews and de-regulatory efforts will be required of RRTFs with stringent oversight from the administration and OMB. Types of reforms, and challenges in implementing them, are discussed below.

Best Analysis. To create less burdensome rules, agencies would ideally conduct unbiased analysis.

- 1) Cost-Benefit Analysis (CBA). Independent agencies issue as many major rules as executive agencies, and they are not subject to mandatory OIRA review of their CBA. Reviews of independent agencies' CBAs would be consistent with the existing executive review of information requests under the Paperwork Reduction Act.<sup>85</sup> While it is often recommended that independent agencies be required to submit CBAs for executive review, there is some disagreement about the approach needed to enact such a requirement, whether through an Executive Order from the President or through Congress.<sup>86</sup>

<sup>85</sup> Institute for Policy Integrity, "Strengthening Regulatory Review: Recommendations for the Trump Administration from Former OIRA Leaders"

<sup>86</sup> Institute for Policy Integrity, "Strengthening Regulatory Review;" Cass R. Sunstein, "5 Smart Ways to Cut Red Tape," *Bloomberg*, January 20, 2016

This should not imply that independent agencies are not conducting CBAs. In response to court rulings against “arbitrary and capricious” rulemakings, independent agencies regularly do conduct CBAs. However, when agencies prepare a CBA, disagreements abound over legitimacy of the model, factors included or not included (e.g., impact on international competition, innovation, jobs; components of indirect costs; cumulative costs) and methods for quantifying qualitative costs as well as benefits. All of this disagreement further bogs down rulemaking and strains agency resources. Independent, dispassionate review of CBAs may increase their utility, however, they remain “position papers” subject to whims of their authors. Ultimately, it seems CBAs have little impact on constraining new burdensome regulation and are often criticized as being inaccurate and failing to capture complete costs of implementation.

One entity that possesses a limited capability to provide unbiased cost estimates is the Congressional Budget Office (CBO). The CBO is responsible for conducting cost estimates for private sector mandates in Federal Legislation, but due to interpretation of the term “enforceable duty” in the Unfunded Mandates Reform Act of 1995, it does not regularly perform cost analysis of legislation that requires companies to comply with federal safety or environmental standards<sup>87</sup>. An exception to this policy occurs when analysis or studies are requested specifically by a Committee Chair. Although such requests are reportedly rare, examples include studies on Corporate Average Fuel Economy Standards or the November 2016 review of “Economic Effects of Canceling Scheduled Changes to Overtime Regulations.” That being said, the CBO lacks the capability to provide comprehensive economic analysis for *all* proposed legislation that imposes regulatory burden on the private sector.

- 2) Best Science. Although reforms often mandate that analyses include “best science”, what constitutes “best science” can be debatable. Therefore, use of “best science” will still produce contested rules.
- 3) Examination of Alternatives. The benefits of an examination of alternatives are intuitive: *“If an agency has not identified and analyzed a number of approaches, it may mean the agency has settled on an approach without ever knowing if there are more effective ways to solve the problem.”*<sup>88</sup> In addition to past reform efforts, recent legislative proposals include provisions to require agencies to analyze regulatory alternatives.<sup>89</sup> But, an analysis of traditional command-and-control alternatives suffer from

<sup>87</sup> Congressional Budget Office, “Private-Sector Mandates in Federal Legislation”, January 2013

<sup>88</sup> Mercatus, “Impact of Regulation”

<sup>89</sup> Speaker Ryan’s “A Better Way” plan and Regulatory Accountability Act, passed by the House in 2011 and proposed again in the 113th Congress (Brookings, “Prospects for Regulatory Reform”)

1415 the same challenges that every CBA suffers from: they are not easily conducted and they require  
 1416 resources: “*neither the costs of regulation nor its benefits are transparent. With outcomes so opaque,*  
 1417 *the task of comparing the effectiveness of rival approaches is daunting.*”<sup>90</sup> An option for agencies may  
 1418 be to include in their analyses market-based alternatives, such as tradable permits (cap and trade  
 1419 systems), which are more straightforward to analyze because marginal costs are easier to measure.<sup>91</sup>  
 1420 Manufacturers would welcome this approach because they tend to prefer markets to drive behavior  
 1421 versus regulation.<sup>92</sup>

1422 4) Cumulative Costs. There are compelling arguments for the need to assess not just the cost of  
 1423 individual regulations, but the cumulative costs as well (as discussed in section 4). However, while the  
 1424 difficulties involved in preparing a CBA of an individual regulation are formidable, a cumulative cost  
 1425 assessment would be exponentially more difficult. In fact, NAM claims that there is “*no established*  
 1426 *technique to measure cumulative burden.*”<sup>93</sup>

1427 5) Innovation. The negative impact of regulation on innovative capacity (and the associated detriment to  
 1428 the economy) is widely accepted. Thus, it is rational for reforms to require regulations to be designed  
 1429 to minimize their impact on innovation. But, like the categories above, this is easier said than done.

1430  
 1431 Public Engagement / Transparency. The benefits of public engagement and transparency of process are  
 1432 compelling, particularly given that manufacturers rightly point out that rules are written by people who “*have*  
 1433 *never spent time in the field implementing them.*”<sup>94</sup> Public engagement also helps agencies to – as NAM  
 1434 suggested – emphasize compliance assistance over enforcement, by helping agencies  
 1435 develop/disseminate compliance tools including: FAQs (“*one of the most helpful documents that regulators*  
 1436 *can develop to enhance compliance*”) and “educational materials”.<sup>95</sup> Unlike other reforms, this category  
 1437 has had more success, but some agencies still avoid public engagement and resist reform, because of the  
 1438 potential problems that may arise from it. For one, public engagement opens up an agency to additional  
 1439 scrutiny, including the potential for endless debate by groups looking to block a new rule. In addition,  
 1440 agencies must be wary of “rent seeking” – firms attempting to influence regulations in their favor.

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<sup>90</sup> NERA/MAPI, “Macroeconomic Impacts”

<sup>91</sup> Harrington, “Grading Estimates”; Wayne B. Gray, “Environmental regulations impose costs on firms, affecting productivity and location but providing significant health benefits,” *IZA World of Labor* 187 (September 2015)

<sup>92</sup> NAM, “Holding US Back”

<sup>93</sup> NAM, “Holding US Back”; authors, however, goes on to offer a technique in this report.

<sup>94</sup> NAM, “Holding US Back”

<sup>95</sup> NAM, “Holding US Back”



1441

1442 Sensitivity to Impact on Small Business. Like many types of reforms, there is widespread support for this

1443 category, but many sources claim that agencies avoid the requirements laid out in reforms such as the

1444 Regulatory Flexibility Act.<sup>96</sup> Again, it is assumed that resources (time and effort) are the reason some

1445 agencies avoid measuring regulatory impacts on small businesses.

1446

1447 Adequate Resources and Oversight. As suggested in Section 4 - History of Reform, the fact that Executive

1448 Orders appear to require the same types of actions over and over again, suggests there may be resistance

1449 to regulatory reform in general. Many sources claim that legislation is needed to mandate reform activities

1450 and that current legislation needs to be tightened up to eliminate interpretation issues. Beyond this, the

1451 overriding issue appears to be resources. In a 2004 report to Congress, CRS wrote: *"the cumulative weight*

1452 *of federal rulemaking requirements is substantial. Currently, dozens of statutes and executive orders*

1453 *govern the federal rulemaking process, requiring numerous forms of analyses and processes before rules*

1454 *can take effect. Those analytical and procedural requirements are not free" ...*<sup>97</sup>

1455 Oversight/watchdog organizations, such as OIRA within OMB, have been created to maintain the integrity

1456 of agency rulemaking efforts, but here too, resources are an issue.<sup>98</sup> If more is demanded of agencies and

1457 in turn, more is demanded of the watchdog, bottlenecks could stymie removal of regulations. Suggestions

1458 that Congress be accountable for all regulations are countered by the argument that Congress does not

1459 have the capacity to be the ultimate arbiter of all regulations or even major ones.<sup>99</sup> Similarly, although

1460 sources suggest that the courts be allowed a role in regulatory reform, the same bottleneck potential

1461 applies here as well.<sup>100</sup>

1462

1463 *6c. Existing Rules: Reducing Existing Regulatory Burden through Retrospective Review*

1464 As stated in Section 4, reducing the existing regulatory burden is perceived by some to be more critical

1465 than reforming the process of creating new regulations.<sup>101</sup> Retrospective reviews of existing regulations

1466 have been required since the Carter administration, but like reforms for rulemaking processes to create

1467 new regulations, retrospective reviews are not often conducted.

<sup>96</sup> 146-NAM; Am. Forest, "Smarter Regulation"; CRS, "Federal Regulatory Reform"

<sup>97</sup> CRS, "Federal Regulatory Reform"

<sup>98</sup> Am. Forest, "Smarter Regulation"; Philip A. Wallach, "An Opportune Moment for Regulatory Reform", Brookings, April 2014

<sup>99</sup> Brookings, "Prospects for Regulatory Reform"

<sup>100</sup> Brookings, "An Opportune Moment"

<sup>101</sup> NAM, "Holding US Back"; NERA/MAPI, "Macroeconomic Impacts"

1468 The need for retrospective review is straightforward. Although public engagement is critical before rules are  
 1469 written as discussed above, agencies and regulated industries can only work with *hypotheticals* before  
 1470 rules are promulgated. Retrospective reviews give agencies and the regulated community an opportunity  
 1471 to assess a regulation's *actual* impact – costs and benefits – using real numbers and experiences.  
 1472 “Lookbacks” would allow agencies to examine unintended costs as well as identify (and ameliorate)  
 1473 unnecessarily burdensome compliance requirements.

1474 There are many reasons why meaningful retrospective reviews are rare.<sup>102</sup> The overriding reason is  
 1475 probably the same as for new rules (above): there are “insufficient incentives”<sup>103</sup> to overcome strained  
 1476 resources. Some sources suggest that agencies are biased and that “*External funds must be provided to*  
 1477 *give disinterested researchers an incentive to conduct unbiased and independent studies.*”<sup>104</sup>

1478 Several models were suggested including a non-partisan entity like the Congressional Budget Office (CBO)  
 1479 which avoids making policy recommendations and focuses on unbiased analysis, which in this case would  
 1480 be identifying regulations that are in need of reform or elimination.<sup>105</sup> Regulatory Reform Task Forces  
 1481 (RRTFs) have been formed (via EO 13777) within each agency and they can help play this role. However,  
 1482 we caution that RRTFs will be hampered due to their lack of sufficient independence from their agency, and  
 1483 their lack of a single, focused mission. For the majority of RRTFs, we predict the duties will be a secondary  
 1484 or tertiary duty which only receives attention during periods of high scrutiny. Therefore, we assert that  
 1485 constant attention and oversight of their efforts will be required in order to make sufficient progress.

1486 Another mechanism for forcing retrospective review is a “2 for 1” (also known as PAYGO, “one-in, two-out”,  
 1487 or Cut-Go) type mandate that requires the elimination of regulations or *costs* of existing regulations to offset  
 1488 the burdens of a new regulation, as required in President Trump’s Executive Order 13771. Countries such  
 1489 as the UK, Canada, the Netherlands, and Australia have implemented a version of this program.<sup>106</sup> In  
 1490 Senate testimony, Senator Mark Warner claimed that the UK went from being the epitome of regulatory

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<sup>102</sup> RFF, “Grading Estimates”; A July 2007 report issued by the GAO found that federal agencies’ reviews of their current rules, including the periodic reviews required under section 610, are neither as useful nor as open to public involvement as they should be (Randall Lutter, “The Role of Retrospective Analysis and Review in Regulatory Policy”, Mercatus, April 2012 referring to GAO, “Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews”, GAO-07-791 (Washington, DC: GPO, July 2007), 35, 43–44)

<sup>103</sup> RFF, “Grading Estimates”

<sup>104</sup> RFF, “Grading Estimates”

<sup>105</sup> Philip A. Wallach, “An Opportune Moment for Regulatory Reform”, Brookings, April 2014

<sup>106</sup> All 4 nations focus on cutting *costs* not number of regulations; Australia, Canada, and the Netherlands focus on red-tape or administrative costs; UK’s definition is broader but focuses heavily on red-tape.

1491 oppression to surpassing the US in international competitiveness in part because of its ongoing PAYGO-  
1492 type policies.<sup>107</sup>

1493

1494 *6d. Regulatory Reforms Require Manufacturers and Regulators to Work Together (“on the ground”*  
1495 *perspective).*

1496 RFI respondents provided a multitude of examples of unnecessary compliance burdens. Our review is not  
1497 able to evaluate the substance of all the complaints or the soundness of all recommended solutions, but the  
1498 large number of examples suggests there is a significant opportunity for regulatory reform.

1499 Rather than focus on retrospective reviews as a re-litigation of the validity of a regulation (i.e., focusing  
1500 solely on analysis of costs and benefits or arguing over the regulatory objectives), agencies could adopt the  
1501 practice of working together with the regulated community – manufacturers, in this case — to understand  
1502 real world burdens (including unintended ones) and to derive commonsense solutions collaboratively.  
1503 Given the myriad challenges in *creating* a good rule (as discussed above), lookbacks with stakeholders  
1504 give agencies another opportunity to work toward the goal of having regulations that impose the least  
1505 burdens.<sup>108</sup>

1506 This suggestion fits with EO 13777- *“In performing the evaluation [of existing regulations], each Regulatory*  
1507 *Reform Task Force shall seek input and other assistance... from entities significantly affected by Federal*  
1508 *regulations...”* In addition, former OIRA head Cass Sunstein recently wrote: *“Because the White House*  
1509 *itself lacks the capacity to scrutinize the stock of existing regulations, the Trump administration was smart*  
1510 *to call for task forces within each agency to do that — and to require them to engage with the public to see*  
1511 *which regulations are really causing trouble.”*<sup>109</sup>

1512

1513 This is also very much in line with other nations’ reform policies (such as PAYGO described above). In  
1514 every case, government works with the regulated community to identify unnecessary burdens, because, as  
1515 one former UK government official said, *“In the UK, by focusing on **how** we regulated, rather than*  
1516 *just **what** we regulated, we were able to drive enormous cost reductions without sacrificing protections. By*  
1517 *simplifying forms and processes, compliance became much less costly without any underlying regulatory*

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<sup>107</sup> *How Best to Advance the Public Interest: Hearing before the Committee on Homeland Security And Governmental Affairs, U.S. Senate, 112th Cong., (2011)*

<sup>108</sup> Clinton EO 12866: “Each agency shall tailor its regulations to impose the least burden on society...”

<sup>109</sup> Cass R. Sunstein, “Trump’s Safe and Sane ‘Regulatory Reform’ Idea,” *Bloomberg*, March 3, 2017

changes or compromising mission.”<sup>110</sup> [bold added] This official also observes that the cultural change required to accomplish this reform should not be underestimated: “Those who work in regulatory policy often focus on designing new regulatory ideas. Typically, they don’t systematically look for ways to reduce the costs of regulations that are already on the books.”

RFI respondents also call for agencies to review existing regulations with stakeholders.<sup>111</sup> One association suggested that a better relationship with manufacturers may help agencies to be accommodating without sacrificing their missions: “state regulators [in Indiana, Louisiana, Ohio, and Texas are] more knowledgeable about ... steel manufacturing, or more willing to take the time to become knowledgeable... Armed with superior knowledge, state personnel often understand the impracticability or inapplicability of certain controls or requirements, and are more often open to allowing alternate compliance options that reach the same goal through the use of less burdensome means.” (112-SMA)

Examples from RFI responses of commonsensical suggestions for reform (that might be surfaced during a collaborative lookback) include the following (organized by category):

- Lack of knowledge about how industry operates; unreasonable or impractical
  - “EPA’s Risk Management Program rule and other regulations require manufacturers to interact with Local Emergency Planning Committees (LEPCs). [But] there are no LEPCs in many areas. Of the 100 counties in North Carolina, for example, only 40 have functioning LEPCs.” (53-ACMA)
  - [Re OSHA’s Hazardous Air Contaminants Standards; for employers seeking to meet through an engineering calculation or evaluation they conduct] “Powered ventilation is generally the most effective and widely used technology to limit exposures to hazardous airborne substances in composites manufacturing workplaces. PPE [personal protective equipment] is also employed when the nature of the work limits the ability of employers to achieve safe exposure levels via ventilation alone. However, several industry employers have been cited by OSHA for using PPE when they have not “proven” that engineering control would not be sufficiently effective...” (53-ACMA)
  - “FDA regulatory provisions implementing the Food Safety Modernization Act (FSMA) require sellers (farmers and food processors) to obtain from their customers (downstream food processors

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<sup>110</sup> Jitinder Kohli former chief executive of Britain’s Better Regulation Executive (Jitinder Kohli, “What President Trump Can Learn From The UK About Reducing Regulations,” Forbes, January 27, 2017)

<sup>111</sup> For e.g., 48-RFF with regard to EPA and NAAQS; 133- Plastics Industry Association with regard to EPA and flexible air permitting; and 53-American Composites Manufacturers Association regarding EPA emission modeling.

and distributors) certain “written assurances” [re food safety hazards] on an annual basis... An analysis by the Grocery Manufacturers Association determined that just the provisions in [one of several specific regulations] would require individual firms to obtain thousands or even millions of assurances every year...” (122-AHPA)

- [Regarding Non-Complying Lots -- 40 CFR. § 770.20(f), which requires fabricators that received notification from a panel producer of panels that failed an emissions test, to inform customers that their finished products contained these panels.] “First, by the time the fabricator receives the panel producer’s notification, the panels almost certainly no longer exist as panels. Instead, the fabricator will almost certainly have cut up the affected panels it received into component parts, incorporated those component parts into finished goods, and shipped those finished goods. Second, the affected panels are untraceable once they are incorporated into finished goods. A fabricator does not track which panels go into which finished goods... Third, in the fabrication process the panels are covered with veneers or other coatings. This means that it is no longer feasible to test the panels accurately for compliance with the emissions limits. Fourth, the fabricator’s notification is very likely to be completely unnecessary, because by the time the customer receives its notification, the affected panels will probably have aged to the point that they now meet the emissions limits.” (67-AHFA)

- [Regarding CWA §316(b)- Cooling Water Intake Structures (CWIS) -- Entrainment “Best Technology Available” (BTA) for facilities withdrawing less than 125 MGD] “Facilities withdrawing less than 125 MGD are not required to submit entrainment information however the permitting authority is still required to make a determination about the BTA to minimize entrainment... Permitting authorities generally lack the technical expertise in such areas, so it requires the permittees to provide the permitting authority with adequate technical information to support the BTA determination. A 52-week entrainment study can range from \$140,000 to \$410,000.” (147-US Steel)

- “[Regarding] Toxic Substances Control Act (TSCA) regulation... Chemical Data Reporting (CDR) regulations require exceptionally detailed monitoring, recording, and reporting of the chemical make-up of our members’ steel and steel coatings, raw materials...) It is overly burdensome to the steel industry to report on the general safety of a product that has been widely produced for several centuries and whose chemical makeup is well known and that poses little risk from exposure.” (92-AISI)

- 1577 ○ *“EPA should ensure remediation cleanup standards are reasonably achievable... for example*
- 1578 *cleanup standards may be set below background concentrations that can never be achieved at a*
- 1579 *cleanup site until sources in the wider area are controlled...” (76-Boeing)*
- 1580 ○ *“FDA has formally acknowledged under various circumstances that reliance on batch records is an*
- 1581 *accurate and practical method for assuring that finished food products meet required compositional*
- 1582 *specifications for ingredients that are chemically complex or for which no validated test method*
- 1583 *exists... [But] during inspections of firms under 21 CFR Part 111, FDA often pushes firms to*
- 1584 *implement expensive chemical testing for such ingredients (which would cost at least hundreds*
- 1585 *and potentially thousands of dollars per batch of product) – or to prove that no such chemical test*
- 1586 *method exists (an exercise that is expensive and pointless, since it’s impossible to prove a*
- 1587 *negative and it is very rare for valid test methods to exist for chemically complex food ingredients,*
- 1588 *especially in a chemically complex matrix).” (122-AHPA)*
- 1589
- 1590 – Inconsistency in enforcement
- 1591 ○ *“Differential enforcement of a regulatory requirement across geographies (i.e., inspectors*
- 1592 *interpreting a regulation differently in two different manufacturing locations) is so troubling to*
- 1593 *compliance officials.”<sup>112</sup>*
- 1594 ○ *“Inconsistent Federal implementation of the RCRA Corrective Action process from region to region*
- 1595 *and site to site... causes... increased cost and lost opportunities due to unpredictable or longer*
- 1596 *time periods for addressing impacts to the environment.” (147-US Steel)*
- 1597
- 1598 – Antiquated rules
- 1599 ○ *“The current Leak Detection and Repair (LDAR) rules require point-by-point monitoring for leaks*
- 1600 *(Method 21) for every LDAR component (valves, pumps, compressor seals, pressure relief*
- 1601 *devices, etc.). This is very time consuming and inefficient. Infrared cameras (IR camera) are now*
- 1602 *voluntarily used in manufacturing to detect leaks much more quickly and efficiently. The use of*
- 1603 *these IR cameras should be a technology option to replace the current antiquated LDAR rules.”*
- 1604 *(89-IECA)*
- 1605
- 1606 – Technology requirement is too expensive or unproven (unrealistic assumptions or cost is too high)

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<sup>112</sup> NAM, “Holding US Back”

- *“FDA regulation 21 CFR 111, Current Good Manufacturing Practice (cGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, includes Section 111.605 (a) and (b) ... requires that all electronic records comply with 21 CFR 11, a burdensome and complex requirement to validate computer systems that was developed for drug manufacturers. The software and hardware validation requirements are costly, difficult to maintain, and fail to provide added security... Small and midsize dietary supplement manufacturers that lack the resources to validate computer systems are burdened with maintaining hard copies and using hand-written records, which is a costly, inefficient, and unnecessary clerical obligation...” (63-CRN)*
- *“The PSD BACT evaluation process, spelled out through EPA guidance, should not include unproven technologies employed in other countries that have not been demonstrated as commercially feasible or effective at controlling emission in the U.S. Requiring domestic facilities to conduct technology reviews and costly feasibility analyses of technologies utilized in countries that do not have the same rigorous air pollution control and permitting requirements, places unreasonable permitting demands and delays on the already lengthy U.S. permitting process.” (92-AISI)*
- Complex, onerous processes, e.g., unnecessary recordkeeping
  - *“In past years we dedicated the majority of our environmental resources to emission reduction equipment that has dramatically reduced our impact on the environment. In more recent years, the majority of our environmental resources have been dedicated to monitoring and record keeping. Reducing the frequency of monitoring, and reducing the amount of recordkeeping and reporting would be very beneficial. We believe that we can adequately demonstrate ongoing and continuous compliance with reduced levels of monitoring and recordkeeping.” (112-SMA)*
  - *“For permitting projects... USEPA and States ask for endless pieces of information that are not necessary to issue a permit or approve a submittal; and are beyond what is required by statute and the implementing regulations. Frequently, the agencies indicate the information is needed to address questions or concerns from third parties—‘we need this information because somebody may ask about it or because it would be nice to know.’” (147-US Steel)*
  - *“Review and streamline data requirements to ensure that only data that is required for a permit decision is required to be submitted.” (79-Northrup Grumman)*

- *“Record Keeping Mandate on EPA Air Permitted Standby Engines: 40 CFR Part 51 (Subpart A) ... Standby engines rarely operate but companies, by law, are required to report emissions data... in 2016, a company reported total emissions from emergency engines (generators and fire pumps) as follows. [Table shows emissions sum= 0.005716 tons per year] The company estimates that it takes \$500 (5 times \$100 per engine) per year to monitor, report, and do maintenance as EPA instructs them to do. Given the costs and given the emission volume, it cost about \$90,000 per ton of emissions.” (89-IECA)*

#### *6e. Reforming the Permitting Process*

According to RFI respondents, *“permitting requirements are numerous and quite onerous.”* (112-SMA) Permitting - particularly related to the Clean Air Act and Clean Water Acts – was the most frequently cited concern, and often identified as a top priority regulatory burden. The Clean Air Act New Source Review (NSR) was described by many as the biggest permitting problem.

In section 5 we discussed concerns related to specific regulations and permitting rules, such as NSR and Title V of the Clean Air Act. In this section we discuss two overarching themes that arise throughout federal permitting. The first is *overlap, duplication and lack of coordination* among agencies, permitting processes, and reporting requirements. The second is *uncertainty* related to permitting processes.

*Overlap, Duplication and Coordination.* Many RFI respondents claimed that EPA “second-guesses” state decisions. (170-APF) *“Even in cases where a state issues CAA permits under an EPA-approved [state implementation plan], there are instances when decisions made by the permitting authority are re-evaluated and revisited by EPA, duplicating the efforts of the agencies and adding uncertainty for the permittee.”* (126-API)

In addition, there were other examples cited of *“overlapping jurisdiction of federal agencies and programs”* (146-NAM) such as:

- *“Aspects of RCRA and CAA permits”* (158-CKRC)
- *“NSR and Title V permits can have significant overlap...”* (109-Valero)
- *“EPA and the U.S. Army Corps of Engineers: Water and wetlands.”* (146-NAM)
- *“EPA’s Integrated Risk Information System, EPA’s risk evaluation programs under the Toxic Substances Control Act, the CDC’s Agency for Toxic Substances and Disease Registry Toxicological*



1666 *Profiles program, and NIH's National Toxicology Program Office of Report on Carcinogens have largely*  
1667 *redundant missions.” (53-ACMA)*

1668 In some cases, multiple regulations or agencies require the same information: *“Companies are often*  
1669 *required to separately report the same information to multiple regulatory offices and programs, including at*  
1670 *the federal, state and local level. For example, data on air emissions are typically reported as part of permit*  
1671 *compliance reports, to state air emission inventories, and to EPA's Toxic Release Inventory program.”*  
1672 *(152-AWC)*

1673 And a related issue is the lack of coordination of the review process when more than one agency is  
1674 involved: *“US Army Corps of Engineers has authority for Section 404 permitting. However, in order to get*  
1675 *the permit, review and consultation is required for multiple other federal agencies... all raising issues about*  
1676 *maintaining sufficient bird and fish habitat.” (126-API)*

1677 *Overlap, Duplication and Coordination - Potential Solutions.* Many respondents suggested that federal  
1678 agencies (primarily EPA) should defer to states in order to: *“...reduce, if not eliminate, federal second-*  
1679 *guessing. Substitute individual permit oversight with federal programmatic overview of state adherence to*  
1680 *permitting requirements. States should be evaluated on how their program is performing, not*  
1681 *micromanaged on each and every permit decision.” (170-APF).*

1682 In other cases, where multiple agencies must be involved, many respondents suggested something similar  
1683 to FAST-41 type provisions:

- 1684 – *“Designate Lead Agency to coordinate responsibilities among multiple agencies involved in project*  
1685 *reviews.”*  
1686 – *“Provide for concurrent reviews by agencies, rather than sequential reviews”.<sup>113</sup>*

1687 Respondents also offered the following best practice examples:

- 1688 – *“Ohio EPA piloted a program in which it took normally sequential steps in permit processing and*  
1689 *executed them in parallel, significantly reducing overall permit processing time.” (170-APF)*  
1690 – *“Indiana Department of Environmental Management's air program processes construction permit*  
1691 *applications and associated Title V permit modification for projects concurrently...” (147-US Steel)*

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<sup>113</sup> 107-COC; Also the Water Resources Reform and Development Act of 2014 is another FAST-41 type model for permitting reform according to 109-Valero: *“...overhauled the Corps' planning process by creating a strict three-year deadline and \$3 million federal cost limit for feasibility studies. It required different levels of Corps review to occur concurrently and eliminated duplicative requirements, such as multiple cost-estimates and a reconnaissance study. [Also] designated the Corps to be the lead agency coordinating reviews for civil works projects...”*

1692 – *“The California Unified Program Agency (CUPA) consolidates hazardous waste and hazardous*  
1693 *materials requirements of multiple programs into a single regulatory entity. The result is simplified*  
1694 *permitting, reduced regulatory complexities and reduced management burden.”* (79-Northrup  
1695 Grumman)

1696 And one association suggested a “reporting portal” created by EPA with state and local regulators to “allow  
1697 manufacturers to report information needed by regulatory programs only once.” (152-AWC)

1698 Several RFI respondents suggested that a specific coordinator is needed, such as a federal office  
1699 responsible for permit coordination (106-AFS), or an EPA ombudsman: *“This supervisory body could*  
1700 *[provide] the regulated community with a means for coordination across various environmental media*  
1701 *(water, air, etc) and across various agencies (e.g., EPA, Army Corps of Engineers, Fish & Wildlife),*  
1702 *perhaps even including state and local agencies or authorities.”* (76-Boeing)

1703 A slightly different suggestion is for Commerce to create a centralized system of publicly available data  
1704 needed by all companies for site permitting to “streamline ... the front end” of the process. (128-Pugh)

1705 *Uncertainty Related to Permit Processes.* Permitting challenges are exacerbated by uncertainty, about  
1706 which many RFI respondents complained. Uncertainty comes from inter-related issues driven by complexity  
1707 such as “case-by-case” or “one-off” reviews that “reinvent the wheel.” There is also a general lack of  
1708 consistency, which then contributes to uncertain timelines, which itself is exacerbated by the threat of delay  
1709 driven by public protest/litigation. This complex situation is then made more uncertain by lack of  
1710 transparency/communication. While, uncertainty is also a problem in non-permitting regulations (discussed  
1711 above), it appears to be a significant and systemic problem in environment-related permitting:

1712 *“Environmental permitting has many sources of uncertainty, including ... timing, procedures, the roles of*  
1713 *various agencies in multi-agency review projects, and the data that the permitting authorities use and rely*  
1714 *upon in making permitting decisions. Often, this variability is based on the views and expectations of a*  
1715 *particular regional office or specific employee or office within EPA. Other times, the requirements can apply*  
1716 *Agency-wide yet still create uncertainty. EPA, for example, is inconsistent in its data demands and the*  
1717 *procedures by which it approves projects...”* (112-SMA)

1718 Environmental permitting is so complex, respondents described having to hire several consultants and  
1719 lawyers to help “navigate” the “elaborate mazes” that permit regulations have become. (170-APF)

1720 Moreover, this appears to be true of “even simple modifications”. (112-SMA) One association wrote,  
1721 *“Obtaining a permit for just one CAA program alone (the NSR program) can require the permittee to review*

1722 *nearly 700 posted guidance documents...* (170-APF) For manufacturing firms, the uncertainty of the  
 1723 permitting duration, which can take years, may be the greatest challenge. *“The lack of certainty as to when*  
 1724 *the permit will be issued... create(s) significant burden, compliance difficulty, and business uncertainty...”*  
 1725 (126-API) Permitting delays are partly driven by complexity and lack of coordination as discussed above.  
 1726 But some respondents blamed agency staff for contributing to the problem, claiming staff can *“sit on an*  
 1727 *application until their allotted time is almost up before looking at it regardless of how minor or simple the*  
 1728 *task.”* (114-AGC) On the other hand, other respondents claimed that delays are sometimes due to  
 1729 insufficient staffing resources at permitting agencies. (79-Northrup Grumman; 126-API; 123-3M)

1730 Delays are not only driven by the agency or agencies. Lawsuits or “Not-in-my-backyard activism” (107-  
 1731 COC) are a significant permitting issue: *“Even where a permit remains valid pending resolution of the*  
 1732 *litigation, significant uncertainty can be introduced into the process of building or expanding a facility and it*  
 1733 *can take years to resolve all issues”* (136-AFPM). While this is not under the control of regulatory agencies,  
 1734 it does increase the uncertainty for manufacturers in making investment decisions.

1735 Lastly, according to respondents, EPA’s lack of straightforward communication adds to manufacturers’  
 1736 burden: *“EPA does not provide clarity on its procedures and information requirements. These transparency*  
 1737 *problems are significantly compounded when EPA changes its requirements through Agency-generated*  
 1738 *guidance without notice to the applicants or the ability to comment on, or ask questions about, the*  
 1739 *guidance.”* (112-SMA) As one example, an association explained that a Congressional requirement that  
 1740 EPA publish all state implementation plans (SIPs) was put in place *“because it was virtually impossible to*  
 1741 *determine which regulations were currently approved as part of the SIP. This lack of transparency serves to*  
 1742 *delay projects simply because discerning what regulations apply presents its own challenge.”*<sup>114</sup>

1743 *Uncertainty – Potential Solutions.* FAST-41 is often raised as a step in the right direction for permitting  
 1744 reform. Established under Title 41 of the Fixing America’s Surface Transportation (FAST) Act (42 U.S.C. §  
 1745 4370m), FAST-41 was designed to improve the timeliness, predictability, and transparency of the Federal  
 1746 environmental review and authorization process for “covered” infrastructure projects.<sup>115</sup>

1747 FAST-41 created a new Federal Permitting Improvement Council (FPISC), with representation from Deputy  
 1748 Secretary-level members and led by a Presidentially appointed Executive Director. It also created agency  
 1749 Chief Environmental Review and Permitting Officers (CERPOs). Covered projects voluntarily gain access

<sup>114</sup> CAA Section 110(h)(1), requires “EPA to assemble and publish all” SIPs; but EPA is not complying (170-APF)

<sup>115</sup> <https://www.permits.performance.gov/about/fast-41>

1750 to improved authorization and environmental review processes such as early consultation, coordinated  
1751 projects plans, project timetables, public Dashboard tracking,<sup>116</sup> and dispute resolution procedures.

1752 Covered projects are defined as any activity in the United States that requires authorization or  
1753 environmental review by a Federal agency<sup>117</sup>:

- 1754 • Involving construction of *infrastructure* in a designated sector
- 1755 • that is subject to NEPA, and
  - 1756 ○ Does not qualify for an abbreviated review process and is likely to cost more than \$200M;
  - 1757 or
  - 1758 ○ Is of a size/complexity likely to benefit from enhanced oversight/coordination in the opinion
  - 1759 of the Council, including:
    - 1760 ▪ Projects likely to require an Environmental Impact Statement
    - 1761 ▪ Projects likely to require reviews from more than 2 Federal agencies.

1762 Infrastructure includes (with some exemptions): manufacturing projects as well as renewable energy  
1763 production, conventional energy productions, electricity transmission, surface transportation, aviation, ports  
1764 and waterways, water resource projects, broadband, pipelines, aviation, and any other sector determined  
1765 by a majority vote of the FPISC.

1766 The project is new, with the inventory of existing covered projects just added to the Dashboard in  
1767 September 2016. For that reason, one commenter recommended “*revisit[ing] lessons learned from FAST*  
1768 *41 (sic) permit streamlining later when the FAST 41 program is more mature.*” (128-Pugh) At the same  
1769 time the U.S. Chamber of Commerce directly asked that “*the administration’s permit streamlining efforts are*  
1770 *consistent with FAST-41 activities already being administered by the Office of Management and Budget.*”  
1771 (107-COC). NAM noted the potential value of implementing in concert the Executive Order 13755,  
1772 “Expediting Environmental Reviews and Approvals for High Priority Infrastructure Projects” and FAST-41.  
1773 (146-NAM)

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<sup>116</sup> <https://www.permits.performance.gov/projects>

<sup>117</sup> An authorization is defined as any license, permit, approval, finding, determination, or other administrative decision issued by an agency that

- is required or authorized under Federal law in order to site, construct, reconstruct, or commence operations of a covered project administered by a Federal agency, or
- in the case of a State that chooses to participate in the environmental review and authorization... a State agency.

1774 Given the short history of FAST-41 and the strict definition of covered projects, the manufacturing  
1775 community very rarely shares in its benefits. Several of FAST-41's key provisions (107-COC) would be  
1776 extremely beneficial if they were to be applied to manufacturing industry permitting:

- 1777 – *“Establish a permitting timetable, including intermediate and final completion dates”;*
- 1778 – *“Require that agencies involve themselves in the [permitting review] process early and comment*  
1779 *early, avoiding eleventh-hour objections that can restart the entire review timetable”;*
- 1780 – *“Reduce the statute of limitations to challenge a project review from six years to two years.”*

1781 RFI respondents echoed these types of recommendations. Florida offers a best practice model, illustrating  
1782 that an efficient permitting process is possible: *“The SNAP (Simplified Nimble Accelerated Permitting)*  
1783 *process, used by state and municipal agencies in central Florida engages in streamlined, efficient and rapid*  
1784 *construction permitting... transform[ing] an onerous and time consuming process into a reasonably*  
1785 *straightforward and user friendly permit acquisition process.”* (79-Northrup Grumman)

1786 An oft-discussed FAST-41 provision – the “searchable, online ‘dashboard’ to track the status of projects  
1787 during the environmental review and permitting process” (107-COC) – addresses transparency. In  
1788 addition, a respondent cited a similar best practice in this area by a federal agency: *“The FCC has most of*  
1789 *its experimental license application process available on-line. It is easy to see that an application is in the*  
1790 *system, and any comments or requests are also visible. The history of most experimental licenses is*  
1791 *available, going back several years.”* (79-Northrup Grumman)

1792 To address over-complexity respondents suggested various types of permitting standardization as well as  
1793 best practice examples:

- 1794 ○ *“Replace uncertain case-by-case permit review programs with standardized regulatory decisions that*  
1795 *are periodically updated through rulemaking after public notice and comment.”* (112-SMA)
- 1796 ○ *“Develop pre-approved specifications for permits to simplify and shorten the permit process.”* (79-  
1797 Northrup Grumman)
- 1798 ○ Offer *“general permits that companies can opt into for standard pieces of equipment...”* (170-APF)
- 1799 ○ *“U.S. EPA should promote and directly facilitate issuance of innovative air quality permits by*  
1800 *state/regional permitting authorities, especially permits that “advance- approve” changes at*  
1801 *manufacturing facilities.”* (123-3M)

- Streamlined permitting for “minor” projects are offered by the Pennsylvania Department of Environmental Protection (online self-registration forms using templates) and the State of Texas (permit-by-rule program) (158-CKRC)

In addition, one respondent suggested that “Federal agencies should implement Lean [Six Sigma] practices to streamline permitting” and noted that EPA regional offices are attempting to do this. The respondent goes on to say Lean can help agencies reduce uncertainty and inefficiency and shorten schedules and points to the Arizona Department of Environmental Quality as having had success with Lean efforts. (76-Boeing)

In addition to reducing time limit for challenging a permit from 6 years to 2 years as described above, there were a few other recommendations related to objectors to projects. One association related a case where a firm settled a lawsuit brought by an environmental group even though the regulatory agency had found that the facility had done nothing wrong. The association suggested: *“The applicable provisions of the major environmental statutes must be revised to introduce reasonable but tough thresholds to control the right of third parties to unreasonably intervene resulting in delays and expenses to industry. The thresholds must be based on local agency negligence, fraudulent/unlawful behavior or inappropriate influence.”* (89-IECA)

Also, because of the potential of a lengthy permitting process, lack of “grandfather” protection can be exploited by objectors and is a recommended reform: *“Without [grandfather] protection, project opponents will have an incentive to delay the permitting process as long as possible in the hope that the area will be designated NA [nonattainment] before a final permit can be issued. A more consistent grandfathering approach would ensure that companies do not spend years trying to obtain a PSD permit, only to reach the end of the process and find they now need to get an NA NSR permit (with offsets that may not be available) rather than a PSD permit.”* (48-RFF)

#### *6f. Section Summary*

A series of important themes emerge from the analysis in this section. First, previous attempts at reform have had little success. Reform initiatives have prescribed reasonable principles for effective rulemaking – such as the use of cost-benefit analysis, examining alternatives, retrospective reviews, etc. – but those mandates have not eliminated complaints about regulations or minimized regulatory burdens. Factors that undermine previous reform efforts include: debate over cost-benefit models, methodologies, and assumptions; a lack of agency resources and incentives to comply fully with all rulemaking requirements;

1832 and a lack of power and resources in oversight organizations to compel compliance across all federal  
1833 regulations.

## 7. Summary and Recommendations

### Analysis and Findings

The urgency for regulatory and permitting reform is growing. A 2017 industry study found that most manufacturers perceive their regulatory burden to have increased significantly, such that reducing their current burden is more imperative than reducing the cost of new regulations.<sup>118</sup> In most cases, industry respondents to a RFI issued by the Department for public input on these issues did not question the need to protect the environment, human health or worker safety, but they expressed concern about how to achieve those objectives. They identified numerous regulatory and permitting problems that include:

- Onerous and lengthy permitting processes that increase cost, add uncertainty, and inhibit investment in and expansion of manufacturing facilities;
- Inadequately designed rules that are impractical, unrealistic, inflexible, ambiguous or lack understanding of how industry operates;
- Unnecessary aspects of rules, or unnecessary stringency, not required to achieve environmental or other regulatory objectives;
- Overlap and duplication between permitting processes and agencies; and
- Overly strict or punitive interpretations of guidance, policies or regulations that is often counter to a pro-growth interpretation.

After having conducted this thorough review of all comments provided, the Department recommends ~~#####~~ sets of regulations and permitting issues as being the top priorities for reform. Reform efforts designed to address the increasing regulatory burden have prescribed reasonable principles for effective rulemaking – such as the use of cost-benefit analysis, examining alternatives, retrospective reviews, etc. – but have had limited success. Factors that undermine reform efforts include: debate over cost-benefit models, methodologies, and assumptions; a lack of agency resources and incentives to comply fully with all rulemaking requirements; and a lack of power and resources in oversight organizations to compel compliance with these principles.

However, the most important factor may be that some regulators do not appear to embrace the goal of “least burden”, based on the numerous examples given by RFI respondents of unnecessary, unreasonable,

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<sup>118</sup> National Association of Manufacturers, “Holding US Back”



1861 outdated or impractical requirements. Only by *working with* the regulated community (manufacturers in this  
1862 case), before and importantly *after* a rule is promulgated, can agencies address the “real world” / “front-line”  
1863 impacts of their requirements. This collaborative review is distinct from retrospective reviews or analyses,  
1864 which are internal efforts. Agencies who meet regularly with manufacturers to learn about the effects of  
1865 their rules on business operations, can then work collaboratively with them to re-form requirements to be  
1866 practical and commonsensical - yet still effective. The regulatory reform programs of nations’ such as the  
1867 UK, the Netherlands, Canada, and Australia demonstrate initiatives that strive to see regulations from  
1868 industry’s point of view and make burden reduction a priority.

1869 The same approach - of working with the regulated community - also applies to permitting, and several  
1870 specific improvement opportunities were highlighted based on the experiences of manufacturers. Fast 41 is  
1871 a model for the approach we ultimately recommend, including appointing one single lead agency to  
1872 coordinate across government, requiring concurrent reviews by multiple agencies, use of a web portal to  
1873 enhance visibility of the approval process, establishing explicit timetables, and setting a reasonable statute  
1874 of limitations for project objections.

1875 Respondents also offered examples of state programs as best practice models. For example, The  
1876 California Unified Program Agency (CUPA) reduces regulatory burden and simplifies permitting processes  
1877 by consolidating the requirements for multiple programs (hazardous waste and hazardous materials) into a  
1878 single regulatory entity; the Pennsylvania Department of Environmental Protection (PADEP) has an online,  
1879 self-registering permitting process for minor projects; the Arizona Department of Environmental Quality  
1880 implements Lean practices; and the Indiana Department of Environmental Management and Ohio EPA  
1881 have piloted or implemented permitting processes where steps are taken in parallel, rather than  
1882 sequentially.

#### 1883 Recommendations

1884 The Department recommends that each agency’s Regulatory Reform Taskforce (RRTF) review *all* relevant  
1885 detailed comments received in response to the Department’s RFI<sup>119</sup> (RFI) and deliver an “action plan” to  
1886 the administration not later than September 30, 2017. Action plans should outline proposals to address  
1887 outstanding issues identified in this report or justify why action cannot or should not be taken. Agency  
1888 action plans should pay particular attention to correcting perceived burdens in the following Areas of  
1889 Emphasis list as well as those identified in Section 5b of this report. Items on these two priority lists were

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<sup>119</sup> <https://www.regulations.gov/docket?D=DOC-2017-0001>; docket ID DOC-2017-0001

distilled from hundreds of submissions and selected for special emphasis due to their massive economic impact on industries throughout the economy. Each agency's RRTF should prioritize a response to these particular items and must include in their action plan a description of specific actions which could be taken to lessen the burden created by them. In the first year, agency leadership should update the President monthly on the status of their efforts regarding these tasks. While these lists are by no means comprehensive, they represent a targeted first step to quickly address the problem of over regulation.

In addition, the Department recommends creating an annual, open forum between industry leaders and all federal regulatory agencies to evaluate progress. There is a long overdue need for consultations with industry to determine where regulatory burdens are becoming most oppressive and to isolate specific actions the federal government can take to reduce onerous regulations and hasten permitting. Industry has repeatedly expressed its appreciation of the Trump Administration's regulatory reform effort and the trust it has in the Department of Commerce to listen and bring the voice of business to this effort. Because of this, the Department of Commerce recommends that it, along other regulatory agencies, continually evaluate progress and re-attack the problem areas. Similar to Kentucky's "Red Tape Reduction Initiative", federal agencies should collect, review, and act on recommendations from industry. Input from these annual "check-ins" will guide the continuing burden reduction efforts of RRTFs and ensure regulators are moving in the right direction while allowing for policy changes as needed.

Finally, to further advance recent successes with expediting permitting, the Department recommends expansion of the definition of projects that qualify as "covered projects" under Title 41 of the Fixing America's Surface Transportation Act (FAST Act or "Fast 41")<sup>120</sup> to include: "projects the construction of which will result in a significant, immediate economic benefit to the United States." Immediate economic benefit could be defined as funded projects which are ready for groundbreaking within 24-48 months where sponsors can demonstrate direct and indirect benefits to the domestic economy of greater than \$200 million. The exact definition could be refined further by OMB in consultation with the Federal Permitting Improvement Steering Council (FPISC). The FAST Act contains various provisions aimed at streamlining the environmental review process, with improved agency coordination through creation of a Coordinated Project Plan and a Permitting Dashboard which serves as a centralized information page for pending projects, as well as opportunities to better coordinate with state environmental documentation. Expansion of the definition of covered projects to include those which result in immediate economic benefit to the

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<sup>120</sup> 42 USC §41003 et seq.

1919 United States would help to further goals of expanding the domestic economy and lessening permitting  
1920 burdens for manufacturers seeking domestic expansion of their operations.

1921

1922

1923 **8. Actions being Taken by Regulatory Agencies**

1924 As noted in section 3C, several agencies provided written comments to the Department as a result of the  
1925 outreach effort. Seven of the agencies identified specific actions they are taking to reduce regulatory  
1926 burden or streamline permitting. More detail on the actions can be found in Appendix 4. Note that the  
1927 actions being taken may address areas other than those identified in the responses to the RFI.

1928 *DOC/ BIS, NOAA, PTO*

1929 1. See Appendix 4.

1930 *HHS/FDA*

1931 2. Reducing the regulatory burden of Inspections: PMA Critical-to-Quality Program

1932 3. Reducing regulatory burdens through adoption of ISO 13485

1933 4. Reducing regulatory burden through the Medical Device Single Audit Program (MDSAP)

1934 *DOT/PHMSA*

1935 1. Collaborating with stakeholders, including industry, by partnering through the use of technical  
1936 safety consensus standards that are adopted into regulations. Consensus standards are based on  
1937 committees of government, industry, and manufacturers that come together collaboratively in  
1938 consensus to agree upon methods, means, techniques, materials, and technologies.

1939 2. Administering performance based safety regulations that in most cases stand the test of time for  
1940 several decades.

1941 3. Conducting Research and Development to bring products to market and inform regulatory  
1942 improvements.

1943 4. Using a special permit process that allows for deviations from regulations, as long as safety  
1944 equivalency is maintained.

1945 5. Enhancing communication through outreach to operators, trade associations, public safety  
1946 advocacy groups, and cooperation with other governmental agencies.

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1948 *EPA*

1949 1. Continuing to improve review of State Implementation Plans (SIPs)

1950 2. Continuing its process toward finalizing the Title V Petitions Rulemaking

- 1951 3. Revising guidance on Ozone and PM<sub>2.5</sub> Significant Impact Levels
- 1952 4. Revising technical guidance on Model Emission Rates for Precursors of Ozone and Secondary
- 1953 PM<sub>2.5</sub>
- 1954 5. Improving a Data Management Tool for Permitted Emissions Limits & Controls
- 1955 6. Planning to communicate and conduct outreach to promote flexible air permitting options
- 1956 7. Proposing revisions of NPDES Applications and Program Updates Rule
- 1957 8. Considering a process to streamline NPDES Permit Application Forms
- 1958 9. Proposing to provide NPDES Technical Assistance to Affected Manufacturing Facilities:
- 1959 10. Considering the initiation of a LEAN process for NPDES applications
- 1960 11. Streamlining a RCRA Permit Renewal Process
- 1961 12. Accelerating clean-up of contaminated sites using a RCRA Facilities Investigation Remedy
- 1962 Selection Track (RCRA FIRST business improvement process)
- 1963 13. Providing a standardized PCB Facility Approval Streamlining Toolbox (PCB FAST) (through
- 1964 application of lean tools)
- 1965 14. Considering support to State and Local air permitting authorities on Flexible Air Permits
- 1966 15. Considering streamlining NPDES permit application forms for all industrial sectors
- 1967 16. Proposing to provide technical assistance to new manufacturing facilities for NPDES training and
- 1968 information technology tools
- 1969 *FCC*
- 1970 1. Reduce regulatory burdens
- 1971 a. Five-year waiver to broadband Internet access service providers with 250,000 or fewer
- 1972 broadband connections from the enhanced reporting requirements adopted in the 2015
- 1973 Title II Order.
- 1974 b. Reform certain outdated rules applicable to the 800 MHz Cellular Service providers, which
- 1975 included eliminating unnecessary rules and burdens related to application filings, domestic
- 1976 and international coordination, and comparative renewal.
- 1977 c. Streamline and eliminate certain international reporting requirements by proposing to (1)
- 1978 eliminate the Traffic and Revenue Reports and (2) streamline the Circuit Capacity Reports,
- 1979 which will lessen the regulatory requirements on international telecommunications service
- 1980 providers.

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2. Commission actions to streamline permitting processes
  - a. Released a Public Notice that seeks comment on how the Commission could streamline and expedite the process that governs the deployment of broadband infrastructure.
  - b. Plans to vote on Chairman Pai’s proposal to streamline the rules that govern the deployment of wireless broadband infrastructure. The Chairman’s plan proposes to expedite state and local approval of infrastructure deployment applications and streamline rules to advance 5G wireless broadband network deployment.
  - c. Plans to vote on Chairman Pai’s plans to streamline and facilitate the deployment of wireline broadband networks, including by asking whether the FCC should consider using its authority to preempt any unnecessary state and local regulations that are stifling broadband network deployment.

1995    **9. Appendices**

1996

1997    Appendix 1 – Presidential Memorandum (as published)

1998

1999    Appendix 2 - RFI (as published)

2000

2001    Appendix 3 – Minutes from the MEP National Advisory Board Session with Earl Comstock

2002

2003    Appendix 4 - Comments from Regulatory and Other Agencies in Response to Department of Commerce  
2004    Coordination

2005

2006    Appendix 5 - Regulatory Reform Efforts Grouped by Reform Category

2007

2008    Appendix 6 - Abbreviations Used in References to RFI Responses

2009

2010 Appendix 1 – Presidential Memorandum (as published)

2011

2012 **The White House**

2013 Office of the Press Secretary

2014 For Immediate Release

2015 January 24, 2017

2016 Presidential Memorandum Streamlining Permitting and Reducing Regulatory Burdens

2017 for Domestic Manufacturing

2018 January 24, 2017

2019 MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND

2020 AGENCIES

2021 SUBJECT: Streamlining Permitting and Reducing Regulatory Burdens for Domestic

2022 Manufacturing

2023 By the authority vested in me as President by the Constitution and the laws of the

2024 United States of America, I hereby direct the following:

2025 Section 1. Purpose. This memorandum directs executive departments and agencies

2026 (agencies) to support the expansion of manufacturing in the United States through

2027 expedited reviews of and approvals for proposals to construct or expand

2028 manufacturing facilities and through reductions in regulatory burdens affecting

2029 domestic manufacturing.

2030 Sec. 2. Stakeholder Consultation on Streamlining Permitting. The Secretary of

2031 Commerce shall conduct outreach to stakeholders concerning the impact of Federal

2032 regulations on domestic manufacturing and shall solicit comments from the public for a

2033 period not to exceed 60 days concerning Federal actions to streamline permitting and

2034 reduce regulatory burdens for domestic manufacturers. As part of this process, the

2035 Secretary of Commerce shall coordinate with the Secretaries of Agriculture and

2036 Energy, the Administrator of the Environmental Protection Agency, the Director of the



2037 Office of Management and Budget, the Administrator of the Small Business  
2038 Administration, and such other agency heads as may be appropriate.

2039 Sec. 3. Permit Streamlining Action Plan. Within 60 days after completion of the  
2040 process described in section 2 of this memorandum, the Secretary of Commerce shall  
2041 submit a report to the President setting forth a plan to streamline Federal permitting  
2042 processes for domestic manufacturing and to reduce regulatory burdens affecting  
2043 domestic manufacturers. The report should identify priority actions as well as  
2044 recommended deadlines for completing actions. The report also may include  
2045 recommendations for any necessary changes to existing regulations or statutes, as  
2046 well as actions to change policies, practices, or procedures that can be taken  
2047 immediately under existing authority.

2048 Sec. 4. General Provisions. (a) Nothing in this memorandum shall be construed to  
2049 impair or otherwise affect:

2050 (i) the authority granted by law to an executive department or agency, or the  
2051 head thereof; or

2052 (ii) the functions of the Director of the Office of Management and Budget relating  
2053 to budgetary, administrative, or legislative proposals.

2054 (b) This memorandum shall be implemented consistent with applicable laws and  
2055 subject to the availability of appropriations.

2056 (c) This memorandum is not intended to, and does not, create any right or benefit,  
2057 substantive or procedural, enforceable at law or in equity by any party against the  
2058 United States, its departments, agencies, or entities, its officers, employees, or  
2059 agents, or any other person.

2060 (d) The Secretary of Commerce is hereby authorized and directed to publish this  
2061 memorandum in the Federal Register.

2062 DONALD J. TRUMP

2063

2064 **Appendix 2 – Text of the RFI as published in the Federal Register**

2065 [2017-045160 and at Regulations.gov, docket DOC-2017-0001, on March 7, 2017]

2066 DEPARTMENT OF COMMERCE Office of Policy and Strategic Planning [Docket Number: 170302221–  
2067 7221–01] Impact of Federal Regulations on Domestic Manufacturing AGENCY: Office of Policy and  
2068 Strategic Planning, Department of Commerce.

2069 ACTION: Notice; Request for Information (RFI).

2070 SUMMARY: The Department of Commerce is seeking information on the impact of Federal permitting  
2071 requirements on the construction and expansion of domestic manufacturing facilities and on regulations  
2072 that adversely impact domestic manufacturers. As directed by President Trump's Memorandum of January  
2073 24, 2017, "Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing," the  
2074 Secretary of Commerce, in coordination with the Secretaries of Agriculture and Energy, the Administrator of  
2075 the Environmental Protection Agency, the Director of the Office of Management and Budget, the  
2076 Administrator of the Small Business Administration, and other appropriate agency heads, is conducting  
2077 outreach to stakeholders concerning the impact of Federal regulations on domestic manufacturing, and is  
2078 soliciting comments from the public concerning Federal actions to streamline permitting for the construction  
2079 and expansion of domestic manufacturing facilities and to reduce regulatory burdens for domestic  
2080 manufacturers. Responses to this RFI— which will be posted at [http:// www.regulations.gov](http://www.regulations.gov)—will inform the  
2081 report of the Secretary of Commerce to the President, required under the Presidential Memorandum,  
2082 setting forth a plan to streamline Federal permitting processes for domestic manufacturing and to reduce  
2083 regulatory burdens affecting domestic manufacturers.

2084 DATES: Comments must be received by 5 p.m. Eastern time on March 31, 2017.

2085 ADDRESSES: The preferred method for submission of comments is via [http:// www.regulations.gov](http://www.regulations.gov) (at the  
2086 home page, enter DOC–2017–0001 in the "Search" box, click the "Comment Now!" icon, complete the  
2087 required fields, and enter or attach your comments). Alternatively, comments may be sent: Via mail carrier  
2088 to The Office of Policy and Strategic Planning, Department of Commerce, H.C. Hoover Building Rm. 5863,  
2089 1401 Constitution Ave. NW., Washington, DC. 20230. All submissions, including attachments and other  
2090 supporting materials, will become part of the public record and subject to public disclosure. Sensitive  
2091 personal information, such as account numbers or Social Security numbers, or names of other individuals,  
2092 should not be included. Submissions will not be edited to remove any identifying or contact information. Do

not submit confidential business information, or otherwise sensitive or protected information. Attachments to electronic comments will be accepted in Microsoft Word or Excel, or Adobe PDF formats only. Please do not submit additional materials. Comments containing references, studies, research, and other empirical data that are not widely published should include electronic copies of the referenced materials. All comments received in response to this RFI will be made available publicly at [http:// www.regulations.gov](http://www.regulations.gov).

FOR FURTHER INFORMATION CONTACT: For questions about this notice, contact: Carter Halfman, U.S. Department of Commerce, Office of Policy and Strategic Planning, at 202–482–7466. Please direct media inquiries to the Department of Commerce Office of Public Affairs at 202–482–4883, or [publicaffairs@doc.gov](mailto:publicaffairs@doc.gov).

SUPPLEMENTARY INFORMATION: President Trump’s Memorandum of January 24, 2017, “Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing” (82 FR 8667) directs the Secretary of Commerce to conduct outreach to stakeholders concerning the impact of Federal regulations on domestic manufacturing. The Department of Commerce is soliciting comments from the public concerning Federal actions to streamline permitting and reduce regulatory burdens for domestic manufacturers. For the purposes of this effort, “domestic manufacturers” refers to private businesses located in the United States (and its territories) engaged in the mechanical, physical, or chemical transformation of materials, substances, or components into new products, consistent with the 2017 North American Industry Classification System (NAICS) definition of Sector 31–33: Manufacturing. Responses to this RFI will inform the Secretary’s report to the President which will set forth guidelines for Federal permitting and regulatory agencies to streamline Federal permitting processes for domestic manufacturing and reduce regulatory burdens affecting domestic manufacturers. The plan will be coordinated with related activities under existing laws (e.g., FAST–41 1) and executive actions (e.g., Executive Order 13771 on “Reducing Regulation and Controlling Regulatory Costs,” (82 FR 9339, Jan. 30, 2017)).

## RFI

Given the nature and importance of the Presidential Memorandum, the Secretary requests information from stakeholders about how the construction, operation, and expansion of domestic manufacturing facilities are affected by (1) the process of acquiring Federal permits required for the construction, expansion, or operation of such facilities and (2) the burdens of complying with Federal regulations for manufacturing facility construction, expansion, or operation. Through this RFI, the Department is seeking information from stakeholders (such as manufacturers, trade associations, and other interested parties) about the Federal

2123 permitting process and regulatory burdens affecting domestic manufacturing. The Secretary seeks  
2124 information that will assist the Department in developing a proposal to reduce regulatory burdens and  
2125 streamline or otherwise improve the permitting process by understanding the cumulative burden of federal  
2126 regulations and permits and by improving efficiency, transparency, and certainty in the process. You may  
2127 respond to any, all or none of the following questions/requests for information, and may address related  
2128 topics. Please identify the questions or topic areas each of your comments addresses. These questions are  
2129 directed towards domestic manufacturers and their stakeholders. Responses may include estimates.  
2130 Please indicate where the response is an estimate. Respondents may organize their submissions in  
2131 response to this RFI in any manner, and all responses that comply with the requirements listed in the  
2132 DATES and ADDRESSES sections of this notice will be considered.

2133 **General Information:**

- 2134 a. NAICS code(s)
- 2135 b. What do you manufacture?
- 2136 c. Where are your facilities located?
- 2137 d. How many employees?
- 2138 e. Approximate sales revenue?

2139 **Manufacturing Permitting Process**

- 2140 1. How many permits from a Federal agency are required to build, expand or operate your manufacturing  
2141 facilities? Which Federal agencies require permits and how long does it take to obtain them?
- 2142 2. Do any of the Federal permits overlap with (or duplicate) other federal permits or those required by State  
2143 or local agencies? If the answer is yes, how many permits? From which Federal agencies?
- 2144 3. Briefly describe the most onerous part of your permitting process.
- 2145 4. If you could make one change to the Federal permitting process applicable to your manufacturing  
2146 business or facilities, what would it be? How could the permitting process be modified to better suit your  
2147 needs?
- 2148 5. Are there Federal, State, or local agencies that you have worked with on permitting whose practices  
2149 should be widely implemented? What is it you like about those practices?

2150 **Regulatory Burden/Compliance:**

2151 1. Please list the top four regulations that you believe are most burdensome for your manufacturing  
2152 business. Please identify the agency that issues each one. Specific citation of codes from the Code of  
2153 Federal Regulations would be appreciated.

2154 2. How could regulatory compliance be simplified within your industry or sector?

2155 3. Please provide any other specific recommendations, not addressed by the questions above, that you  
2156 believe would help reduce unnecessary Federal agency regulation of your business.

2157 Dated: March 2, 2017. Earl Comstock, Director of Policy and Strategic Planning. [FR Doc. 2017–04516  
2158 Filed 3–3–17; 11:15 am]

2159 BILLING CODE 3510–17–P

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Appendix 3 – Minutes from the MEP National Advisory Board Meeting, March 7, 2017

**Presidential Memoranda**

***Speaker: Phil Singerman, NIST Associate Director for Innovation and Industry Services, and Earl Comstock, Director, Office of Policy and Strategic Planning, U.S. Department of Commerce***

Mr. Comstock discussed the recent Presidential memoranda seeking to minimize regulatory burden on manufacturers. An RFI was published designed to elicit responses from the community of stakeholders on the subject. DOC will be preparing a report on how to streamline the regulatory process for improving manufacturing.

RFI Questions

- Manufacturing Permitting Process:
  - How many permits from a Federal agency are required to build, expand or operate your manufacturing facilities?
  - Which Federal agencies require permits and how long does it take to obtain them?
  - Do any of the Federal permits overlap with (or duplicate) other federal permits or those by State or local agencies?
  - If the answer is yes, how many permits? From which Federal agencies?
  - Briefly describe the most onerous part of your permitting process.
- Regulatory Burden/Compliance:
  - Please list the top four regulations that you believe are most burdensome for your manufacturing business. Please identify the agency that issues each one. *Specific citation of codes from the CFR would be appreciated.*
  - How could regulatory compliance be simplified within your industry or sector?
  - Please provide any other specific recommendations that you believe would help reduce unnecessary Federal agency regulation of your business.

*Discussion*

- 2191 • EPA paperwork was noted as being a major burden. Manufacturers with the means to do so have  
2192 hired a full-time employee to ensure environmental paperwork is done correctly. Most small  
2193 companies cannot afford this expense.
- 2194 • The Alabama Department of Environmental Management does a pretty good job working with  
2195 manufacturers when they can, but often their hands are tied by the EPA.
- 2196 • Environmental restrictions on privately financed facility expansion require information on  
2197 neighboring facilities and past land use, environmental reports, and a costly Environmental  
2198 Insurance Policy on property already owned by the company. Local permits are not a problem to  
2199 obtain.
- 2200 • In the nuclear field, export control is overseen by at least four agencies and their requirements are  
2201 not the same. Jurisdiction over a particular product is often unclear and the cost of acquiring an  
2202 export license varies. Other countries have controls that are just as rigorous but overseen by a  
2203 single agency. The delays in getting an export license have cost American manufacturers work to  
2204 foreign competitors.
- 2205 • Time and resources required for compliance are a major issue, especially legal costs.
- 2206 • Overuse of ITAR labeling creates large amounts of bureaucratic red tape and limits the sharing of  
2207 knowledge.
- 2208 • Many small companies are unaware of all of the regulations that apply to them.
- 2209 • The impact of compliance is much greater on small companies when regulations apply regardless  
2210 of size.
- 2211 • Regulations getting passed down to sub-tier manufacturers that are severely burdened.
- 2212 • SMMs need assistance addressing cybersecurity requirements.
- 2213 • DOC should streamline exporting as much as possible.
- 2214 • DOC's presence on the ground in India has been very helpful and they should advertise their  
2215 services to SMMs.
- 2216 • FARs and DFARs flow down to sub-tier suppliers even if they are not applicable. It creates a legal  
2217 expense and customers do not accept it when a small business takes exception to them. If the  
2218 small business accepts them, they accept an unknown liability.
- 2219
- 2220 Mr. Comstock said that it would be very helpful to get input from the Centers so the Department can get  
2221 something out by June.



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2223

**Appendix 4 – Comments from Regulatory and Other Agencies in Response to Docket Materials**

(Note: Comments have been edited to include only those relevant to manufacturing and the objective of this report. In addition, minor edits have been made to remove prefatory or redundant material.)

*Department of Commerce*

Working through the Department of Commerce's new Regulatory Reform Taskforce, four bureaus provided specific feedback to comments submitted (docket ID DOC-2017-0001), fulfilling a recommendation of this report that all agencies provide individual, public responses comments received in the docket by 30 September 2017. Department of Commerce regulations or processes were mentioned in nine instances across eight comments. The National Oceanographic and Atmospheric Administration (NOAA) received six mentions, followed by one mention each for the U.S. Patent and Trademark Office (USPTO), Bureau of Industry and Security (BIS), and the International Trade Administration (ITA).

*National Oceanographic and Atmospheric Administration*

Several manufacturing project proponents submitted comments principally pertaining to concerns over burdens imposed under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA). There also was a general comment regarding conducting a review of the Coastal Zone Management Act Federal consistency process. Below, NOAA has provided brief responses that address the comments received through the call for information. NOAA is also willing to follow up with the commenters to further discuss and better understand the nature of the concerns raised.

*Endangered Species Act*

1. Williams Companies, Inc noted that “[t]he ESA is a robust and complicated provision that creates uncertainty for project developers..... Williams recommends formation of a working group of key stakeholders to develop recommendations and new guidelines for balancing the protection of [endangered] resources and the need for pipeline infrastructure development.”

Response: NOAA's National Marine Fisheries Service (NMFS) is willing to meet with Williams and other stakeholders to have a discussion regarding the ESA requirements and the areas of uncertainty that are of

2252 concern and explore possible improvements. It is not clear what provisions are of most concern to the  
2253 commenter.

2254 NMFS is open to continuing to explore opportunities to minimize uncertainties regarding ESA requirements  
2255 and to further facilitate achieving ESA goals as efficiently as possible. Toward this end, NMFS currently  
2256 engages with stakeholders and applicants in many ways with regard to the ESA at both a national and  
2257 regional level. At the national level, NMFS has implemented an approach to work aggressively with action  
2258 agencies to explain the ESA, particularly the section 7 consultation process, so that they understand the  
2259 standards and processes and so that we understand their projects and activities. With regard to  
2260 infrastructure pipeline development, NMFS has a position funded by the Department of Transportation to  
2261 facilitate engagement with stakeholders specifically on infrastructure projects. This effort is in its early  
2262 stages and we believe the strong focus on stakeholder engagement in developing best management  
2263 practices will be successful.

2264 In addition, NMFS has convened working groups and working sessions with many different groups,  
2265 including federal agencies, applicants and the states, to discuss the ESA and ways we can improve the  
2266 process. For example, in March 2017, NOAA hosted a joint BOEM-NOAA workshop on best management  
2267 practices for protected marine species and offshore wind development. The workshop was attended by  
2268 over 100 participants, including representatives from the offshore wind industry and environmental non-  
2269 governmental organizations (NGOs), and represented a forward-thinking approach to balancing  
2270 environmental protection with future offshore wind construction project needs. Although the final report has  
2271 not been completed on the outcome of the discussions, attendees discussed industry concerns regarding  
2272 logistical and practical challenges of potential BMPs or mitigation as well as potential for streamlined  
2273 environmental review and permitting. Feedback we received indicates that the discussions were beneficial  
2274 to the attendees, including the offshore wind industry.

2275 Nationally we have engaged with the Department of Defense, Bureau of Ocean Energy Management  
2276 (BOEM), and U.S. Army Corps of Engineers (ACOE) on identifying efficiencies and improvements to the  
2277 ESA and MMPA and have implemented improved processes based in part on these discussions.

2278 Regionally, there are frequent discussions with stakeholders on specific projects and broader topics, and  
2279 we are currently engaging with the Western Governors Association on developing recommendations for  
2280 ESA improvements. The WGA is reporting out this week on their recommendations, based on stakeholder  
2281 discussions, for changes to the ESA and suggestions for improvements to ESA implementation. Those

suggestions will focus on placing a greater emphasis on proactive conservation, increasing flexibility in conservation approaches once species are listed, and working with states and stakeholders in developing a common recovery strategy. We are committed to continuing the dialogue with these and other stakeholders. For example, in mid-May we will engage with the mitigation banking community.

2. The American Petroleum Institute commented that “[e]xecutive agencies should review the issues arising from the Endangered Species Act (ESA) to ensure that it is not arbitrarily used to restrict economic opportunities. State governments have successfully worked with private industry to preserve species and habitat. Executive agencies should assist and defer to state governments as it relates to the ESA. Additional opportunities for reform through legislative or regulatory means include: ending the proliferation of deadline lawsuits and ESA listing actions driven by “sue and settle”; improving the scientific basis and transparency of decisions under the ESA; ensuring greater rigor in scientific and economic/commercial analysis used in making critical habitat decisions; and strengthening incentives for voluntary conservation actions.”

Response: The listing of a species as “endangered” under the ESA brings it within the protections of the act, including the prohibition against “take” of members of that species. “Take” is defined as to “harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or attempt to engage in any such conduct.” Similar prohibitions may be extended to “threatened” species by special rule. Where take would be merely “incidental” to an otherwise lawful activity, however, the act allows for issuance of permits under Section 10 of the act if certain conditions are met and after certain procedures are followed. Another protection that applies to both endangered and threatened species is that proposed federal actions must not jeopardize the continued existence of listed species or destroy or adversely modify any designated “critical habitat.” In the context of the mandated ESA consultation and permitting processes, NMFS works with action agencies (e.g., federal permitting agency), project proponents, and stakeholders to discuss and review projects and make recommendations as necessary to facilitate implementation of the projects under the law.

NMFS works closely with the states on a number of ESA related actions and activities. In 2016, NMFS and the United States Fish and Wildlife Service finalized joint regulations overhauling the process for reviewing petitions under the ESA, and for the first time required that petitioners first give notice to affected states prior to submitting their petitions to the agencies. This notice will give states an opportunity to ensure relevant information is provided to the Services in time to inform review of the matters raised. Also, states

often provide important scientific and biological information that informs the Federal consultation process under the ESA. Furthermore, states routinely comment on and provide input on ESA efforts, such as the consultation process or recovery actions. Further, NMFS currently assists the states through a grant program that provides funding to the states to implement recovery actions for Federally listed species. NMFS is committed to working and coordinating with the states to implement the ESA in an effective manner.

NMFS and US Fish and Wildlife Service and State representatives also co-host the ESA Joint Task Force, an organization that provides a forum to better coordinate with the States and to address issues of common concern.

NMFS is working to identify continued opportunities to improve the efficiency of its statutory and regulatory processes, minimize uncertainties, and improve predictability. For example, NMFS has been working to strengthen incentives for voluntary conservation actions through proposed revisions to the Candidate Conservation Agreements with Assurances (CCAA) policy under the ESA. The revisions will simplify the process of developing and approving CCAAs, which provide incentives for the public to implement specific conservation measures for declining species before they are listed under the ESA.

3. Ameren Corporation made the following comment:

“Authorize Non-Governmental Professionals to Certify Some Environmental Actions --Many state programs capitalize on the expertise of independent professionals as a part of their permitting programs. Ameren recommends that this practice be expanded to the federal level and potentially used for the following approvals: risk assessments and cleanup criteria; habitat and ecological assessments, mitigation measures and best management practices; wetland delineation; remedial actions plans; etc. Appropriate oversight would occur through an in-depth audit process such as that performed by the Internal Revenue Service. Independent Professionals Could Determine when Actions do not Require ESA “Take” Permits. Independent professionals could, for example, in appropriate circumstances certify based on site specific conditions that a proposed project is not likely to impact endangered species and therefore no “take permit” is required from the Fish and Wildlife Service pursuant to the Endangered Species Act.”

Response: This comment seems to pertain to Section 10 of the ESA, which allows the U.S. Fish and Wildlife Service (FWS) or NMFS to issue, upon application by a project proponent, permits for direct take [Section 10(a)(1)(A)] and incidental take [Section 10(a)(1)(B)] of listed species. It is up to the project

proponent whether to apply for a permit. A Section 10 direct take permit benefits the holder by providing a legal defense for take of a listed species consistent with the terms of the permit when the action involved is incidental to, and not the purpose of, an otherwise lawful activity.

Project proponents are not precluded from engaging independent professionals regarding the likely impacts of a project. During the permitting process, including in determining whether the project may be likely to result in take, NMFS routinely relies on information from a variety of sources, including project applicants and their consultants. Information provided by independent professionals is a critical component of our consultation, permits, and recovery efforts under the ESA. Ultimately, of course, project proponents decide based on their own risk assessment whether to seek a permit to authorize any incidental taking that occurs as a result of their activity. However, foregoing seeking a permit may leave the project proponent vulnerable to enforcement action by NMFS or a citizen suit if the project results in take of a listed species.

4. The National Association of Manufacturers notes that “[i]n February 2016, FWS and NOAA Fisheries issued a final rule on critical habitat designation procedures that does not require the presence of physical or biological habitat features. The rule also lowers the threshold for an action to “appreciably diminish” critical habitat and includes alterations that preclude or delay the development of features that do not currently exist. The rule also incorporates a recovery standard which will result in higher mitigation ratios. The designation of critical habitats under the ESA has the potential to affect our access to the two principle (sic) inputs to our manufacturing process: wood fiber and water. Revisions to the ESA habitat designation process should be made that reflect a science-based, common-sense approach to protecting endangered species that also balances the need for continued economic growth. Revisions to the regulation should be made to allow for a reasonable approach to the designation of critical habitats that would replace the final rule on Critical Habitat Designation Procedures.”

5. The Association of General Contractors of America recommends “[repealing] entirely the rule -- “Changes to Endangered Species Act Critical Habitat Designations and ‘Adverse Modification’ Definition” issued by NOAA and U.S. Fish and Wildlife Service on February 11, 2016.

Response to 4 and 5: The ESA imposes mandatory duties on NOAA and FWS (the “Services”) to designate critical habitat to the maximum extent prudent and determinable, and (following such designation) to consult with federal agencies whose actions may affect such habitat to ensure their actions are designed to

2372 avoid destroying or adversely modifying the habitat. Having clear regulations and policies in place  
2373 promotes needed consistency and predictability, and should lead to less litigation and more certainty for all  
2374 interested parties.

2375 In February 2016, the Services finalized a suite of reforms to promote more transparency and predictability  
2376 in the way they designate and protect critical habitat under the ESA. These rules, in part, responded to  
2377 section 6 of Executive Order 13563 (January 18, 2011), which directed the Services to analyze their  
2378 existing regulations and, among other things, modify or streamline them in accordance with what had been  
2379 learned.

2380 First, the Services' revised 50 CFR 424.01, 424.02, and 424.12 (except for paragraph (c)) to clarify the  
2381 procedures and criteria used for designating critical habitat, addressing in particular several key issues that  
2382 had been subject to frequent litigation. This was designed to bring greater transparency and consistency to  
2383 carrying out this mandatory duty under the ESA. Note, that in designating critical habitat for a particular  
2384 species, the Services must clearly articulate, in proposed and final rules, which physical or biological  
2385 features within its occupied habitat are essential to the conservation of the species and the basis for  
2386 including a specific area in the designation of that critical habitat. The regulation draws on the Services'  
2387 decades of experience under prior regulations, responds to various court decisions, and codifies the  
2388 Services' most recent practices.

2389 Second, the Services' regulation defining the standard for "destruction or adverse modification" of critical  
2390 habitat in the interagency consultation process (see 50 CFR 402.02) replaces a regulation that was  
2391 invalidated by two circuit courts of appeal many years ago. The rule made minor modifications to align the  
2392 regulatory definition of "destruction or adverse modification" with the conservation purposes of the ESA  
2393 and the ESA's definition of "critical habitat." The change did not alter the overall meaning of the proposed  
2394 definition. Having a regulatory definition in place is intended to facilitate carrying out the mandatory duty to  
2395 consult with other federal agencies under Section 7(a)(2) of the act, which is required for proposed federal  
2396 actions that may affect designated critical habitat.

2397 The Services also adopted a policy providing notice to the public and guidance to staff as to the factors  
2398 they will consider in weighing possible exclusions from critical habitat designations under Section 4(b)(2) of  
2399 the ESA. Section 4(b)(2) gives a wide degree of discretion to the Secretary to exclude specific areas from  
2400 a critical habitat designation if the benefits of excluding the area outweigh the benefits of including the area.  
2401 This determination is made after consideration of factors such as economic impacts, impacts to national

security, and other relevant factors. This policy promotes consistency and predictability by, among other things, re-affirming the Services' commitment to taking into account plans and partnerships that are put in place to protect habitat. The policy also reflects the Services' commitment to minimize designations on private lands by focusing where possible on federal lands, to avoid unnecessarily causing concerns to private landowners and to focus on those areas where the protection of interagency consultation under Section 7(a)(2) will actually apply. However, the policy is expressly intended to be "non-binding," in that it provides guidance but does not mandate particular outcomes. Therefore, in the context of considering the best available scientific information for a particular species' habitat, the Services retain flexibility to deviate from the policy where it makes sense to do so.

#### *Marine Mammal Protection Act*

1. American Petroleum Institute notes that "[f]or oil and gas operations, even for seismic surveys, the process may be daunting. As you can see in the graphic below, the path to obtaining permits to conduct Atlantic Ocean seismic surveys is convoluted, requiring a company to await completion of an environmental analysis under the National Environmental Policy Act and consultation under the Endangered Species Act. Once those evaluations are complete, the company must then apply to the Bureau of Ocean Energy Management (BOEM) for a seismic survey permit. BOEM's decision on granting the seismic survey permit is contingent upon the company successfully obtaining a permit from the National Marine Fisheries Service (NMFS) for Incidental Harassment Authorization under the Marine Mammal Protection Act and concurrence from potentially-affected states that the seismic survey is consistent with the states' coastal zone management plans under the Coastal Zone Management Act.

This bureaucratic process was particularly costly and burdensome to companies seeking applications to run seismic surveys in the Atlantic Ocean. The inefficiencies in the process were exacerbated by a lack of cooperation and coordination between BOEM and NMFS. In the end, the Obama Administration refused to complete the process and BOEM denied permit applications based on spurious claims of potential environmental harm. As a result, new seismic data upon which to base future leasing and development decisions were not collected and any potential



2431 opening of the Atlantic to oil and gas development, and the resulting jobs that would be created, is  
2432 now unnecessarily delayed.”

2433 Response: Under the President's April 28, 2017 Executive Order on Offshore Energy Development, the  
2434 Secretary of the Interior and the Secretary of Commerce are charged to expedite all stages of consideration  
2435 of Incidental Take Authorization requests, including IHAs and Letters of Authorization regarding and  
2436 Seismic Survey permit applications under MMPA and the Outer Continental Shelf Lands Act, respectively.  
2437 We have implemented some administrative improvements that are already expediting the process. Over  
2438 the next year we intend to implement administrative, policy and regulatory changes that will significantly  
2439 expedite the process for most MMPA incidental take permits and authorizations.

2440 As regards the project cited in the comment, NMFS worked closely with BOEM as a cooperating agency in  
2441 the development of BOEM's Programmatic Environmental Impact Statement (PEIS) for Atlantic Outer  
2442 Continental Shelf Proposed Geological and Geophysical Activities in the Mid-Atlantic and South Atlantic  
2443 Planning Areas This project was particularly challenging and the environmental analyses particularly effort  
2444 intensive because seismic surveys have not previously been conducted in the area. Therefore, significant  
2445 background work was required to prepare environmental analyses as compared to other areas where such  
2446 activities have been ongoing and the subject of extensive prior analysis. NMFS did issue a programmatic  
2447 biological opinion for BOEM's proposed geological and geophysical activities in support of its oil and gas,  
2448 renewable energy, and marine minerals programs in the Mid-and South Atlantic Planning Areas from 2013  
2449 through 2020, as described in the PEIS. The PEIS is designed so that once the initial environmental  
2450 analyses and compliance processes are undertaken and in place, permitting for similar activities in the  
2451 future should be a more iterative, streamlined, process.

2452 2. The National Association of Manufacturers has comments on the National Oceanic and  
2453 Atmospheric Administration's National Marine Fisheries Service (NOAA Fisheries): Updated  
2454 Acoustic Criteria for Level A Takes under the Marine Mammal Protection Act. Specifically, “[t]his  
2455 NOAA Fisheries guidance, issued in August 2016, established new sound thresholds that will limit  
2456 or prevent seismic activity in the Gulf of Mexico, even though seismic operations are essential to  
2457 future energy exploration and development. While it is appropriate to adopt reasonable measures  
2458 that mitigate the potential risks of seismic activity, as responsible companies already do, the new  
2459 NOAA Fisheries criteria disregard key scientific data. The guidance should be withdrawn and  
2460 rewritten.”

2461 Response to 1 and 2: Under the President's April 28, 2017 Executive Order on Offshore Energy  
2462 Development, the Secretary of Commerce is charged with reviewing the Technical Guidance for "Assessing  
2463 the Effects of Anthropogenic Sound on Marine Mammal Hearing: Underwater Acoustic Thresholds for  
2464 Onset of Permanent and Temporary Threshold Shifts."

2465 In August 2016, NMFS published the Technical Guidance cited above. The Technical Guidance is not a  
2466 regulation, nor does it impose legally binding standards, or prevent seismic activity in the Gulf of Mexico. It  
2467 does bring together in one place the best available scientific information for assessing, for purposes of  
2468 authorizing take of marine mammals under the MMPA, whether exposure to certain types of acoustic  
2469 sources (i.e., anthropogenic noise) is likely to result in impacts to marine mammal hearing (i.e., changes in  
2470 their hearing threshold). Threshold in this case is defined as the hearing level above which individual  
2471 marine mammals under NMFS' jurisdiction are predicted to experience injury based on scientific  
2472 information. Exposure to sound may produce elevated hearing thresholds or threshold shifts in mammals.  
2473 If these elevated hearing thresholds are significant, they can result in hearing damage. Hearing damage  
2474 depends on the intensity of the sound, the frequency of the sound, and how long the animal is exposed to  
2475 the sound (duration). Given that marine mammal hearing is essential to their ability to carry on vital life  
2476 functions such as feeding, breeding, and migration, using the best available science to understand the  
2477 impacts of various sound sources and to effectively minimize the impacts to marine mammals is essential  
2478 to their conservation. And given that there are vital national security and economic interests that need to  
2479 use sound in their operations, it is essential that our scientific knowledge be the best available and our  
2480 application of that science be used to mitigate impacts in a practicable manner.

2481 NMFS is looking at a variety of actions to try to make its processes more efficient.

2482 Currently, NMFS' ability to meet the demand for ESA consultations is constrained by resource limitations  
2483 and has resulted in a backlog of consultations in some areas. While NMFS was able to complete 2,500  
2484 consultations in 2016, the demand for this work was over 3,700 consultations.

2485 Under an ESA pilot program in several regions, NMFS has worked to reduce the level of review and  
2486 analysis associated with some consultations. This saves time and ensures decisions are made at the  
2487 lowest organizational level possible thus further reducing the time associated with higher organization level  
2488 reviews. NMFS plans to expand this pilot program to additional regions in the coming year to the extent  
2489 possible within existing resources.

2490 NMFS is also working to increase the number and scope of programmatic consultations under both the  
2491 ESA and Magnuson-Stevens Act. Such programmatic consultations increase the number of projects that  
2492 can be assessed in a quick fashion for impacts on listed species and their habitat and areas important to  
2493 marine fisheries. NMFS' ability to conduct additional such programmatic consultations would require  
2494 additional resources as specific projects often require priority attention to meet action agency and applicant  
2495 timing needs.

2496 NOAA will also work with the Department of the Interior to explore the possibility of further streamlining the  
2497 informal consultation process. The goal of this initiative is to provide Federal action agencies and project  
2498 applicants a time certain period for determining whether an informal consultation is needed or whether the  
2499 permitting process can proceed without waiting for such a consultation.

2500 NMFS is also considering changes to the MMPA that would help clarify statutory requirements for incidental  
2501 harassment authorizations. Specifically, NMFS is looking at whether changes to the standard in the MMPA  
2502 regarding effects could be clarified in a manner that provides greater certainty to applicants and allows  
2503 NMFS to better and more appropriately characterize potential impacts to marine mammals associated with  
2504 projects. This would also result in clearer more legally defensible outcomes for NMFS and the applicants.  
2505 NMFS will also review the Technical Guidance per direction in the Executive Order on Offshore Energy  
2506 Development to ensure we have incorporated the best available science.

2507 As background, in 1998 the first marine mammal hearing thresholds applied by NMFS in MMPA  
2508 authorizations represented a very simplistic understanding of the effects of underwater noise on marine  
2509 mammal hearing. NMFS applied a one size fits all approach, not accounting for different marine mammal  
2510 hearing abilities nor different properties of acoustic sources (seismic air guns and sonar). Over the last 10  
2511 years NMFS has worked with other agencies (US Navy in particular) and academia to improve the data on  
2512 marine mammal hearing and sound source effects through research and modelling to develop a better  
2513 understanding of marine mammal hearing thresholds. The US Navy has pioneered the approach that is  
2514 reflected in our technical guidance.

2515 The thresholds described in the Technical Guidance are only one aspect of the IHA permitting process and  
2516 do not, by themselves, determine the mitigation measures necessary to authorize the take of marine  
2517 mammals to meet MMPA standards for any one project.

The Technical Guidance is meant for use both by project proponents and NMFS analysts when seeking to determine whether and how their activities are expected to result in potential impacts to marine mammal hearing via acoustic exposure. It promotes predictability for the regulated community and consistency across NMFS' permitting actions that allow important activities, such as military readiness activities and oil and gas exploration, to occur consistent with requirements to minimize take of marine mammals. The Guidance was the subject of three independent peer reviews and three public comment periods. Responses to public comments appear at 81 Federal Register 51694 (August 4, 2016).

*Coastal Zone Management Act*

1. Williams Companies, Inc. noted that “[i]nside the Department of Commerce, NOAA's Office for Coastal Management frequently addresses federal consistency determinations in the context of pipeline infrastructure. Because this process introduces cost, timing and uncertainty considerations for the deployment of pipeline infrastructure capital, Williams suggests that the Department of Commerce initiate a separate information gathering process to examine burdens associated with this program as well as opportunities for simplification.”

Response: The Coastal Zone Management Act (CZMA) and its implementing regulations provide a transparent, predictable, and timely process for state review of energy projects in coastal and federal waters. With regard to addressing potential inefficiencies and uncertainty in the federal consistency program, NOAA, in 2006, undertook a comprehensive rulemaking effort to address industry concerns with the Coastal Zone Management Act (CZMA) federal consistency provisions and, among other things, respond to amendments to the CZMA enacted by Congress in the Energy Policy Act of 2005. In particular, the intent of the rulemaking was to: 1) create more streamlined and flexible procedures; 2) minimize duplicative efforts and unnecessary delay; and 3) address recommendations outlined in Vice President Cheney's 2001 Energy Report to President Bush. The Final Rule amended NOAA's federal consistency regulations to impose timeframes for NOAA to decide appeals of state CZMA objections and to clarify other procedural requirements and deadlines. These regulatory changes are working and allow coastal states to consider the national interest in furthering energy infrastructure and give consideration to coastal dependent uses.

Further, NOAA, from time to time, considers changes to the federal consistency regulations. For instance, NOAA issued a Final Rule in 2000 that made many changes to the regulations in response to the 1990 amendments to the CZMA and over twenty years of experience with federal consistency. NOAA issued another Final Rule in 2006 that made specific changes to address industry concerns with the CZMA federal consistency provisions and, among other things, respond to amendments to the CZMA in the Energy Policy Act of 2005. NOAA is currently developing a rulemaking to make a minor correction to the federal consistency appeal regulations to better conform them to the Energy Policy Act of 2005 Amendments to the CZMA.

Over time, and as modified by the 2000 and 2006 rulemakings, the federal consistency provisions within the CZMA and its implementing regulations have worked effectively and efficiently—with states concurring with approximately 95 percent of the thousands of projects they have reviewed under the provisions. In the cases where a state does object, the applicant has the opportunity to appeal the objection to the Secretary of Commerce and the Secretary can overrule the state's objection based on the national interest of the project.

In recent years, leaders from the energy industry have lauded NOAA and the Coastal Zone Management program for working to establish an “efficient and predictable process” in helping to facilitate state approval under the CZMA for Geological and Geophysical seismic surveys along the Southeast coast in 2015.

#### *U.S. Patent and Trademark Office*

US Inventor submitted a four-part comment focused on various USPTO regulations. One part was a recitation of a comment on USPTO's patent fee proposed rule, which US Inventor had submitted to USPTO on December 2, 2016. The other three parts of the comment related to other patent regulations. Below is a brief summary of each of the four parts of US Inventor's comment followed by brief responses from USPTO.

1. US Inventor asks the Secretary to stop USPTO's proposed patent fee increase (published as a Notice of Proposed Rulemaking on October 3, 2016) from taking effect. The organization asks the Secretary to announce that USPTO is subject to Executive Orders 13771 and 13777. They also

2574 state that USPTO should prepare a separate “elasticity analysis” for small businesses and  
2575 calculate costs for its rule for the U.S. economy as a whole.

2576 Response: The USPTO is proposing a modest increase in fees for patent services of approximately 3.7%  
2577 over the five-year horizon contemplated in the rule. The fee adjustments detailed in the USPTO’s Setting  
2578 and Adjusting Patent Fees During Fiscal Year 2017 rule are needed to provide the USPTO with sufficient  
2579 aggregate revenue to recover the aggregate cost of patent operations (based on current projections). The  
2580 proposed fee increase will provide the Office with sufficient resources to fund improvements that will benefit  
2581 stakeholders, regardless of entity size, including enhancing the quality of patent examinations, achieving  
2582 optimal examination times, and modernizing patent IT systems. Additionally, the final rule further expands  
2583 the current nearly 200 discounted fees for small and micro entities fees (who receive 50% and 75%  
2584 discounts respectively by statute), and removes some service fees that are no longer necessary. Public  
2585 comments in response to the notice of proposed rulemaking have been considered in developing the final  
2586 rule, and USPTO also engaged in outreach through its Patent Public Advisory Committee as it was  
2587 developing this fee proposal.

2588 USPTO is subject to and will comply with the President’s executive orders regarding rulemaking (Executive  
2589 Orders 13771 and 13777), and will comply with all requirements of applicable executive orders and OMB  
2590 guidance in issuing any final rule. USPTO designated its proposed rule on patent fees as significant in  
2591 compliance with OMB guidance.

2592 The USPTO follows the guidance set forth in OMB Circular A-4, “Regulatory Analysis,” in determining  
2593 which data to provide in fee setting and adjusting calculations and analyses. USPTO complies with all  
2594 applicable OMB guidance in issuing its rules. USPTO has taken into account input from its stakeholders  
2595 throughout its rulemaking process. USPTO stakeholders are generally supportive of modest fee increases,  
2596 while expanding the number of discounts for small and micro entities, because such increases allow  
2597 USPTO to ensure that it issues the highest quality patents possible in the shortest amount of time. As  
2598 stated above, the proposed fee increase has several benefits to stakeholders, regardless of entity size,  
2599 including enhancing the quality of patent examinations, achieving optimal examination times, and  
2600 modernizing patent IT systems.

2601

2. US Inventor states that the Secretary of Commerce should repeal the PTO's Subject Matter Eligibility Guidelines, pointing to the USPTO webpage that references: 2014 Interim Guidance on Patent Subject Matter Eligibility, July 2015 Update, May 2016 Update, three case law memoranda, four sections of the Manual of Patent Examination Procedure, six sets of examination examples, three quick reference sheets, a chart of Supreme Court and Federal Circuit subject matter eligibility court decisions, and six examiner training modules. The organization states that these guidelines go far beyond what is legally required under 35 U.S.C. § 101 and Supreme Court case law because the guidelines make new law rather than simply applying the law of patent eligibility.

Response: In 2012, in the decision *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court issued a decision outlining a framework for analyzing patent claims to a law of nature under 35 U.S.C. § 101. In 2014, the U.S. Supreme Court issued a decision in *Alice Corp. v. CLS Bank Int'l (Alice)* which used the Mayo framework to analyze claims directed to abstract ideas, which expanded its application and required the USPTO to change its examination policy with respect to subject matter eligibility. As a result, guidance and other associated materials were necessary to establish clear examination procedures and to ensure a consistent application of the subject matter eligibility analysis across 8,200 patent examiners. In December 2014, the USPTO developed its Interim Eligibility Guidance, which was published in the Federal Register (79 FR 241). The USPTO has updated this guidance several times, and also has issued explanatory examples, conducted examiner training, and issued several memoranda addressing recent developments from the U.S. Court of Appeals for the Federal Circuit.

Although public input was not required, the USPTO published the Interim Eligibility Guidance in the Federal Register, and posted the related updates to this guidance, memoranda, training, and examples on its Internet web site. These materials are also used by the public in preparing patent applications and responding to subject matter eligibility issues raised during examination. The USPTO has invited, and continues to invite, public comment on the published Interim Eligibility Guidance (and related updates to this guidance, memoranda, training, and examples) and has held numerous public events to discuss the implementation of the Alice/Mayo framework during examination. Updates to the Interim Eligibility Guidance are based upon these public comments, as well as case law developments. Through public engagement and continued updates to the guidance and training, the USPTO is attempting to bring stability and consistency to the examination procedure in this unsettled area of the law.

- 2631 3. US Inventor requests that the Secretary repeal 37 CFR. §§ 42.1-42.304, which govern certain post-  
2632 grant review proceedings conducted by USPTO's Patent Trial and Appeal Board (PTAB). The  
2633 organization is critical of these post-grant review proceedings and suggests that "PTAB must be  
2634 eliminated."

2635 Response: The America Invents Act (AIA), signed into law on September 16, 2011, established post-grant  
2636 review proceedings and required the USPTO to prescribe regulations for those proceedings. 35 U.S.C. §§  
2637 316, 326. The post-grant proceedings are intended to serve as a quality check on issued patents and to  
2638 offer parties a faster and less expensive alternative to district court litigation. In order to eliminate PTAB  
2639 and the PTAB rules, Congress would have to amend the AIA. The AIA was enacted following several years  
2640 of congressional hearings and engagement with stakeholders. It was passed 89-9 in the Senate and 304-  
2641 117 in the House, with wide bipartisan support. We are aware of no pending legislation to eliminate post-  
2642 grant review proceedings.

2643 The USPTO promulgated 37 CFR. §§ 42.1-42.304 to carry out the statutory mandate of the AIA. However,  
2644 these regulations, like all regulations, are not permanent. The USPTO is engaged with stakeholders to  
2645 determine whether and how to refine them. For example, the USPTO has solicited public input and has  
2646 made modifications to the initial rules to attempt to ensure that the proceedings are as fair as possible  
2647 within the USPTO's statutory mandate. Additionally, the USPTO has recently launched a wide-ranging  
2648 PTAB Procedural Reform Initiative to further shape and improve the proceedings based upon historical  
2649 data and user experience. Information on this initiative can be found at [https://www.uspto.gov/patents-  
2650 application-process/patent-trial-and-appeal-board/ptab-procedural-reform-initiative](https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-procedural-reform-initiative).

2651 Although the PTAB proceedings are not without cost for the parties involved, they were created as a less  
2652 expensive alternative to district court litigation. In fact, it is estimated that PTAB proceedings are about one  
2653 tenth of the cost of district court proceedings. A patent owner is not required to pay any fees to the USPTO  
2654 in defending its patent in a post-grant review proceeding. However, a petitioner is required to pay over  
2655 \$20,000, and the USPTO has proposed increasing this fee to \$30,000.

- 2656 4. US Inventor states that the Secretary should repeal and replace 37 CFR. § 1.56 as proposed in the  
2657 notice of proposed rulemaking PTO-P-2011-0030, 81 Fed. Reg. 74987 (Oct. 28, 2016). The  
2658 organization states that the current version of 37 CFR. § 1.56 is outdated and overbroad, and that  
2659 the proposed rule imposes a burden on inventors that is far more onerous—and requires far more  
2660 documents to be submitted to the PTO—than is required under current binding case law, namely,



Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc). They also state that USPTO has delayed in amending § 1.56 to bring the agency into compliance with the six-year old Therasense decision because the USPTO initially proposed to amend this rule shortly after the decision in 2011, and then in October 2016, the USPTO issued the second notice of proposed rulemaking.

Response: On May 25, 2011, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) issued an en banc decision in Therasense v. Becton, Dickinson and Co. (Therasense) regarding the inequitable conduct defense to patent infringement. This doctrine states that a court will not enforce a patent where the patent was procured through fraud, such as intentionally withholding material prior art from the USPTO during prosecution of the patent application. In Therasense, the court set forth a but-for materiality standard for inequitable conduct. Specifically, prior art is material if the USPTO would not allow a claim in a patent application had it been aware of the undisclosed prior art.

Similar to the Federal Circuit's inequitable conduct doctrine, the USPTO's duty of disclosure under 37 CFR. § 1.56 requires patent applicants to disclose all information known to them to be material to patentability. On July 21, 2011, the USPTO published a notice of proposed rulemaking in the Federal Register (76 FR 43631) to change § 1.56. In particular, the notice proposed to adopt the Therasense materiality standard for inequitable conduct in court proceedings as the USPTO's materiality standard for the duty of disclosure in USPTO proceedings.

In September 2011, prior to the adoption of any final rule by the USPTO to change § 1.56, Congress enacted the Leahy-Smith America Invents Act (AIA), which contained provisions impacting the inequitable conduct doctrine. Additionally, there were case law developments concerning the inequitable conduct doctrine. Based upon these developments, the USPTO determined it should again seek comments from the public on its views on whether it should adopt the Therasense materiality standard as the USPTO's materiality standard for the duty of disclosure in USPTO proceedings. In order to seek these comments, a second notice of proposed rulemaking was published in the Federal Register (81 FR 74987) on October 28, 2016. The USPTO is interested in pursuing amendments to regulations that have a positive impact on the patent system. The USPTO has now received and is considering the public comments on the amendments proposed in the second notice of proposed rulemaking.

2690

2691 *Bureau of Industry and Security*

2692 The National Association of Manufacturers offered a general statement to the Departments of Commerce,  
2693 State and Defense regarding export controls as well as six specific recommendations. The  
2694 recommendations and response from the Bureau of Industry and Security are as follows:

- 2695       • General NAM request to move less sensitive military items from the U.S. Munitions List (USML) to  
2696       the Commerce Control List (CCL)

2697

2698 Response: NAM notes that that “the previous Administration failed to make important systemic changes  
2699 that would remove unnecessary, duplicative and time-consuming licensing procedures that continue to limit  
2700 manufacturers in the United States from being competitive and reliable suppliers to trusted allies and  
2701 partners, undermining the U.S. manufacturing base.” NAM “encourages the Administration to modernize  
2702 fully the U.S. export control system” and notes the aversion to “buying U.S. technologies because of the  
2703 ITAR restrictions that apply to foreign customers.”

2704

2705 NAM is correct to address this comment to all three agencies, because formulation and implementation of  
2706 export control policy is an interagency process. The U.S. Government requires licenses for only a small  
2707 percentage by value of U.S. exports, and it does so to obtain visibility into transactions for national security  
2708 or foreign policy reasons. Both Commerce and State exert controls on further movement of U.S.-origin  
2709 items to protect the integrity of their export controls. BIS supports removal of controls that are unnecessary  
2710 or duplicative but would require interagency agreement on which controls fit that description. BIS also  
2711 supports the ongoing reviews of export control lists to ensure that items that do not ensure the United  
2712 States a critical military or intelligence capability are controlled for export on the CCL, not the USML

2713       1. Simplify encryption controls

2714 Response: BIS shares this goal but past efforts have resulted in protracted interagency negotiations with  
2715 only incremental changes to encryption controls. Encryption is both sensitive and pervasive, and its use  
2716 raises national security and foreign policy (especially human rights) concerns. It is multilaterally controlled  
2717 by the Wassenaar Arrangement, and U.S. controls are administered by the National Security Agency as

well as the Departments of Commerce, State and Defense. NSA has had concerns about the national security and intelligence harms that could be caused by loosening encryption controls, a difficult argument to overcome in interagency discussions. While BIS continues to work with industry groups, Technical Advisory Committees, and government partners on this issue, it is likely a long-term effort

2. Establish an effective program license

Response: With interagency cooperation, it would be possible for BIS to create some kind of an umbrella license for manufacturers that support U.S. government defense and security programs with allies overseas. If concerned agencies decided to pursue this, it would involve changing regulations, government licensing procedures, and possibly internal government organization (e.g., staffing, information technology) to accommodate the reviews necessary for such license applications. The regulatory changes alone would be neither quick nor easy, and would likely require a notice of inquiry with a sixty-day comment period, at least one proposed rule with a sixty-day comment period, development and publication of a final rule with a delayed effective date, likely six months, to allow exporters to update their compliance systems. In each of these publications, BIS would have to work closely with interagency partners to balance U.S. government equities while accommodating, to the greatest extent possible, industry's needs (as expressed in the submitted comments). The concerns that interagency partners have expressed in the past on this are that often the risk of diversion of the goods to an unauthorized end users or end uses outweighs the value of the project license to industry.

Note that as a result of BIS's recent extension of the validity period of export licenses (from two to four years), BIS's Munitions Control Division has been able work with exporters within the existing licensing system to reduce the number of licenses needed per project by projecting out four years' worth of shipments and grouping items by sensitivity level, so that the exporter can support programs using as few as three or four licenses. This lower-impact alternative may be sufficient to meet the need outlined by NAM.

3. Create an intra-company transfer license exception

Response: Theoretically, such an exception would leverage company internal compliance processes and intellectual property controls to safeguard technology transfers the way government licenses currently do.

BIS proposed an intra-company transfer license exception in 2008 (73 FR 57554). An interagency partner, while clearing the proposed rule for publication, expressed reservations about the lack of visibility into

affected transactions and its inability to impose additional conditions on them, and cast doubt on clearance of a final rule without more restrictive provisions. Conversely, the public found the terms of the proposed exception too restrictive and burdensome to be worthwhile. Faced with the near-impossible task of moderating between the two parties to reach compromise, BIS determined that its resources could be put to better use on other initiatives.

4. Negotiate new multilateral controls on intrusion and surveillance items

Response: In 2013, the Wassenaar Arrangement adopted controls on intrusion and surveillance items that raised concern among many stakeholders in the United States. When BIS sought public comment on these controls prior to implementation, there was a generally negative response. The Administration continues the negotiations begun in 2016 with its Wassenaar Arrangement allies to ensure that multilateral controls on cybersecurity items do not impact critical defensive cybersecurity work.

5. Consolidate the licensing jurisdiction for technologies subject to the EAR

Response: It is unclear what NAM means by this; items subject to the EAR are licensed by BIS, and technology required for EAR-controlled software or commodities is also subject to the EAR.

It is possible that NAM is referring to the ITAR's control of defense services (i.e., the furnishing of certain assistance related to defense articles to foreign persons) and its possible application to items that have moved to Commerce jurisdiction. BIS notes that the State Department has published numerous proposals to narrow and clarify the application of their defense services control and seems committed to reaching a final rule. It is also possible that NAM is referring to their support for a broad removal of licensing requirements for allied countries: BIS notes that the U.S. export control agencies are unlikely to agree to such a removal due to concerns over the visibility into such transactions.

6. Revise the ITAR to promote collaboration between commercial companies and government agencies.

BIS cannot address revising the ITAR but would work with State to make any changes to Commerce controls necessitated by increased collaboration.

*International Trade Administration.*

1. The Duty Drawback Coalition seeks the elimination of restrictions on duty drawback and deferral that are provided for in Article 303 of the North American Free Trade Agreement (NAFTA) and implemented under the NAFTA Implementation Act at 19 U.S.C. 1313. Duty drawback is the refund, reduction, or waiver of customs duties on imported merchandise that is subsequently exported, or used in the manufacture of products that are subsequently exported. Duty deferral delays the assessment of customs duties until imports exit a Foreign Trade Zone, bonded warehouse or temporary import status, which typically reduces the amount of duties assessed because of the processing done on the import before it exits. If the exiting good is exported to another country, no duties are assessed.

Response: NAFTA Article 303 limits these benefits when the exports that would trigger them are destined for a NAFTA party. These limitations prevent non-NAFTA imports from receiving the benefit of duty drawback and deferral while also receiving the benefit of preferential tariff treatment under the agreement. With respect to duty drawback, U.S. exporters are limited in the amount they can claim for goods exported to Canada or Mexico. Claims cannot exceed the lowest amount of duties paid or owed to either the United States or to Canada or Mexico (whichever is the good's destination). If tariffs on the U.S. export have been reduced to zero under the agreement, drawback is also zero. With respect to duty deferral, rather than paying no duties for exports from a Foreign Trade Zone, bonded warehouse or temporary import status, U.S. goods exported to Canada or Mexico are assessed a duty equal to the amount that would be assessed on the goods entering the U.S. customs territory for consumption.

The elimination of Article 303's restrictions on duty drawback and deferral, as recommended by the commenters, would require an amendment to the NAFTA. Under NAFTA Article 2202, amendments require the agreement of all NAFTA parties and become an integral part of the agreement only once approved in accordance with the applicable legal procedures of each party. Any modification to Article 303 would require the approval of Canada and Mexico and a change to U.S. law. Regulatory action alone would not be sufficient.

Agreement on the elimination of Article 303, or any amendments to it, could be sought in the context of a NAFTA renegotiation. The U.S. Trade Representative publishes a notice in the Federal Register seeking

public views and holds a hearing on proposed trade agreements. Comments and responses addressing the duty drawback and duty deferral restrictions in Article 303 would be taken into account during the course of the negotiations.

*Department of Energy*

In response to the request made by the Department of Commerce to fulfill its obligations under the Presidential memorandum entitled, “Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing”, the Department of Energy (DOE) provides a brief description of its permitting processes below. DOE notes that while it continually strives to achieve efficiencies in its processes, and seeks comment from the public on its processes through its rulemaking and retrospective review activities, DOE’s permitting processes do not appear to be related to manufacturing, but rather to electric transmission facilities and import/export activities.

The Department of Energy has a small number of permitting programs. On the electricity side, the Department implements delegated presidential authority to issue “Presidential permits” for the construction, operation, maintenance, or connection of electric transmission facilities at the border of the United States. Presidential permits do not grant siting authority, which is typically the role of states; they are limited to the international border crossing. Pursuant to the Federal Power Act, the Department authorizes electricity exports and the coordination of federal authorization for transmission facilities. The coordination program is an Integrated Interagency Pre-Application process wherein project proponents can voluntarily choose to get coordinated feedback from agencies that could authorize the proposed project prior to submitting a formal application. On the natural gas side, pursuant to the Natural Gas Act, the Department authorizes the import and/or export of natural gas (including liquefied natural gas or LNG). The Department’s role concerns movement of the natural gas commodity, not the permitting of natural gas facilities.

*Department of Health and Human Services/Food and Drug Administration*

We are providing the information below from FDA describing reform activities the agency is undertaking to reduce regulatory burden on domestic manufacturing of medical devices.

Reducing the regulatory burden of Inspections: PMA Critical-to-Quality Program. Premarket Approval (PMA) devices are the highest risk medical devices. FDA is developing a new program to streamline and reduce the burdens of inspections of facilities that manufacture PMA devices. Under this program, FDA plans to work with participating PMA applicants to define those characteristics of the device that are critical to product quality, and to understand how the manufacturer controls those characteristics during the design and manufacture of the device. This will promote quality in design and manufacturing, and enable FDA to focus its inspections on those critical characteristics affecting device quality that have been pre-defined in cooperation with the applicant. This will reduce regulatory burden on the manufacturer while protecting patient safety.

Reducing regulatory burdens through adoption of ISO 13485. FDA is exploring adopting ISO 13485, an international Quality System standard specific to medical device manufacturing. In many countries (other than the U.S.), a manufacturer demonstrates acceptable medical device manufacturing practice through conforming with ISO 13485. By comparison, a manufacturer who markets devices in the U.S. has to demonstrate acceptable medical device manufacturing practice by complying with 21 CFR 820 (the medical device Quality System regulations).

Both ISO 13485 and 21 CFR 820 describe requirements for a Quality Management System. While there is considerable overlap between the two, it can be burdensome if a manufacturer must comply with and undergo assessments for both systems. If FDA were to adopt ISO 13485, a manufacturer's burden would be substantially reduced.

Additionally, ISO 13485 may have added benefits. For example, ISO 13485 has a broader scope of risk management than 21 CFR 820, applying risk management throughout product realization. This broader focus can provide benefit to patients and better align with FDA's increasing focus on benefit and risk.

Reducing regulatory burden through the Medical Device Single Audit Program (MDSAP). FDA is a member of the International Medical Device Regulators Forum (IMDRF), which recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. In 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP). MDSAP is a way that medical device

manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. This reduces the burden domestically by reducing the number of inspections that US manufacturers will have to undergo.

The program's main mission is to "...jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers." Audits are conducted by Auditing Organizations authorized by the participating Regulatory Authorities to audit under MDSAP requirements.

MDSAP began as a pilot (January 2014-December 2016). As of January 1, 2017, the MDSAP program is in full implementation. This program minimizes regulatory burden on industry while ensuring appropriate regulatory oversight of medical device manufacturers' quality management systems. The program also promotes more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority.

Currently, FDA uses MDSAP audits in the place of some inspections. This reduces the amount of time regulators spend auditing a firm, eliminating the associated burden and lost productivity associated with an audit.

FDA is looking to expand use of MDSAP audits to include use in place of FDA pre-approval inspections, both for devices and for device regulation aspects of combination products. In addition to eliminating duplicate audits of a firm's manufacturing system, this would also allow manufactures to schedule audits, instead of being dependent on FDA resource availability. This would facilitate the process of bringing a product to market, allowing a manufacturer to strategically align audits with submissions.

*Department of Transportation/Pipeline and Hazardous Material Safety Administration.*

PHMSA's mission is to protect people and the environment by advancing the safe transportation of energy and other hazardous materials that are essential to our daily lives. PHMSA can support the Presidential Memorandums for streamlining permitting and reducing regulatory burden for domestic manufacturing, and encourage the use of American made steel for pipeline construction through:

- Collaboration with stakeholders on consensus standards, which are incorporated into regulation
- Keeping pace with technology



- 2894 • Research and Development to bring products to market and inform regulatory improvements
- 2895 • Utilizing the special permit process to allow for any deviations from regulations when an equivalent
- 2896 level of safety is maintained
- 2897 • Enhancing communication through outreach
- 2898 • Performance based rulemaking improvements

2899

2900 Our responses are noted below under the Office of Pipeline Safety and the Office of Hazardous Materials.

2901

2902 Streamlining Permitting and Reducing Burdens for Domestic Manufacturing. PHMSA was asked to

2903 evaluate regulatory changes already identified and proposed that would support the goal of this President's

2904 Memorandum. And as requested, included are two flow charts depicting the special permitting processes of

2905 the Office of Pipeline Safety (OPS) and Office of Hazardous Materials Safety (OHMS).

2906 Generally, PHMSA can support the President's Memorandum for streamlining permitting and reducing

2907 regulatory burden for domestic manufacturing by:

- 2908
- 2909 • Collaborating with stakeholders, including industry, by partnering through the use of technical
  - 2910 safety consensus standards that are adopted into regulations. Consensus standards are based on
  - 2911 committees of government, industry, and manufacturers that come together collaboratively in
  - 2912 consensus to agree upon methods, means, techniques, materials, and technologies.
  - 2913 • Administering performance based safety regulations that in most cases stand the test of time for
  - 2914 several decades.
  - 2915 • Conducting Research and Development to bring products to market and inform regulatory
  - 2916 improvements.
  - 2917 • Using a special permit process that allows for deviations from regulations, as long as safety
  - 2918 equivalency is maintained.
  - 2919 • Enhancing communication through outreach to operators, trade associations, public safety
  - 2920 advocacy groups, and cooperation with other governmental agencies.

2921

2922 PHMSA, Office of Pipeline Safety. Through the use of performance-based regulations, PHMSA's Office of

2923 Pipeline Safety (OPS) strives to provide operators with the flexibility to use state-of-the-art techniques and

2924 materials that may be produced domestically. OPS regularly incorporates by reference voluntary

consensus standards as a part of its rulemaking activities. Currently, there are approximately 70 standards and specifications that are incorporated by reference in the Federal Pipeline Safety Regulations. Consensus standards are agreed to by committees representing government, industry, and material manufacturers. New or updated standards offer further innovation to reach national goals, and increase the use of new technologies, materials, and management practices that improve the safety and operation of pipelines and related facilities.

OPS regularly reviews updates to currently referenced consensus standards to ensure that their content remains consistent with the intent of the Federal Pipeline Safety Regulations.<sup>121</sup> Further, PHMSA's Pipeline Safety Research and Development program remains influential to safety policy development and new commercial product development. Peer reviewed knowledge from awarded research on technology development and on materials helps inform and improve pipeline rulemaking, Special Permits, and Safety Alerts. Additionally, because PHMSA staff may be directly involved as project managers for technology development of new solutions under PHMSA-awarded research, PHMSA also accepts new technology compliance by operators via Other Technology Notifications.<sup>122</sup>

*Examples of past and future regulatory actions.*

PHMSA recently adopted amendments to pipeline regulations that enhance flexibility that include:

- The current 49 CFR 193 Regulations for LNG facilities require pressure vessels be built to the 1992 edition of ASME Section VIII, which is burdensome to industry. PHMSA has partially relieved this burden by allowing the current edition of ASME with conditions: <https://www.phmsa.dot.gov/faqs/liquefied-natural-gas#d5>. PHMSA also plans to propose fully relieving this burden and to allow the current edition of ASME without condition, and has recently completed a technical study to support this proposal.

*Future potential amendments under consideration include:*

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<sup>121</sup> Previous updates to incorporate industry standards by reference were published in 2015, 2010, 2007, 2006, 2004, 1998, and 1996.

<sup>122</sup> PHMSA has supported R&D that resulted in bringing 26 products to market and led to 22 patents.

- The proposed Plastic Pipe rule would expand the list of allowable materials for the transportation of gas via pipeline to allow operators and manufacturers greater freedom in choosing and creating innovative new piping products.

- With the proposed Presidential Memorandum dated January 24, 2017, all new pipelines, as well as retrofitted, repaired, or expanded pipelines, would use materials and equipment produced in the United States, to the maximum extent possible and to the extent permitted by law. Under the proposed Safety of Gas Transmission and Gathering Line rule, if operators choose to replace pipe in lieu of verifying its integrity, the memorandum would potentially benefit domestic pipeline construction firms. Further, any repairs made per the rule would potentially use materials of United States origin. Likewise, with the proposed Safety of Onshore Hazardous Liquid Pipelines rule, repairs per the revised repair criteria or replacements made in order to make pipelines accommodate in-line inspection tools would need to be performed using United States materials and equipment as much as practicable.

PHMSA, Office of Hazardous Materials Safety. PHMSA's Office of Hazardous Materials Safety (OHMS) continually reviews and revises the U.S. Hazardous Materials Regulations (HMR; 49 CFR Parts 100-185) to ensure the greatest level of flexibility is afforded in areas where the HMR impact manufacturing. The HMR have evolved over time from prescriptive requirements to more modernized performance-based regulatory provisions that include recognition of industry consensus standards (i.e. ASME, ISO, ANSI etc.). PHMSA experts also participate in the development of these consensus standards to ensure transportation safety interests are considered. Based on the scope of the HMR, regulations pertaining to manufacturing are generally limited to the design and construction of packages used to ensure the safe transportation of hazardous materials in commerce. These packages range from small fiberboard boxes to cylinders, drums, and bulk packages such as highway cargo tanks and rail cars. While the HMR's performance-based approach provides inherent flexibility in designing packaging to meet defined performance standards that are generally recognized world-wide, PHMSA works closely with its stakeholders to stay abreast of new technologies and revisions to industry consensus standards. Examples of recent and prospective amendments are below.

*Examples of past and future regulatory actions*

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Recently adopted amendments to the HMR that enhance flexibility include:

- PHMSA expanded the HMR to allow for variations in the manufacture design type of non-refillable metal receptacles in a final rule published on January 21, 2016, titled “Hazardous Materials: Adoption of Special Permits (MAP-21) (RRR)” [81 FR 3635; HM-233F]. Specifically, PHMSA added variations for the manufacture of DOT 2P and 2Q receptacles—known as 2P1 and 2Q1—to better allow for changes in technological advances that were only previously authorized in special permits. Because of this regulatory expansion, manufacturers no longer need to obtain and renew those special permits that were adopted into the HMR.
- Manufacturers of both non-specification nurse tanks and DOT and UN specification packaging were afforded additional flexibility in material of construction and design of packaging when PHMSA incorporated the American Society of Mechanical Engineers 2015 version of the Boiler and Pressure Vessel Code and the 2012 edition of the Transportation Systems for Liquids and Slurries: Pressure Piping Code. These most recent editions were incorporated into the HMR on April 29, 2016, when PHMSA published a direct final rule titled “Hazardous Materials: Incorporation by Reference Edition Update for the American Society of Mechanical Engineers Boiler and Pressure Vessel Code and Transportation Systems for Liquids and Slurries: Pressure Piping Code” [81 FR 25613; HM-261].
- PHMSA plans to expand the regulations and allow for the use of non-bulk combination packages tested with a liquid to be used to transport solids. Currently, § 173.24a(b)(3) allows single or composite non-bulk packages tested with a liquid to be filled with a solid material under certain conditions; however, the HMR does not expand this allowance to combination packages. Once the added regulatory flexibility is adopted, a manufacturer will have greater flexibility in testing a package for solid and liquid hazardous materials. This rulemaking amendment was proposed in a

notice of proposed rulemaking (NPRM) published June 30, 2016, titled “Hazardous Materials: Miscellaneous Petitions for Rulemaking (RRR)” [81 FR 42609; HM-219A]. PHMSA is looking to amend the HMR with these provisions with the publication of a final rule in 2017.

- PHMSA has noted that current regulatory requirements for the manufacture of DOT 4-series specification cylinders are unclear. In an effort to reduce the confusion for manufacturers and provide for greater clarity, PHMSA published a NPRM on July 26, 2016, titled “Hazardous Materials: Miscellaneous Amendments Pertaining to DOT-Specification Cylinders (RRR)” [81 FR 48977; HM-234]. PHMSA is looking to amend the HMR with these provisions with the publication of a final rule in 2017.
- The HMR currently requires a manufacturer to receive approval from the Associate Administrator when making a modification to a UN pressure receptacle design type. In an effort to reduce the burden on a manufacturer, PHMSA has proposed to not require an approval when the requested design modification has already been approved under a UN/ISO standard for the design type. This regulatory flexibility was proposed in an NPRM published on July 26, 2016, titled “Hazardous Materials: Miscellaneous Amendments Pertaining to DOT-Specification Cylinders (RRR)” [81 FR 48977; HM-234]. PHMSA is looking to amend the HMR with these provisions with the publication of a final rule in 2017.
- In an effort to expand regulatory flexibility, PHMSA has proposed to allow water pump system tanks manufactured to American National Standards Institute (ANSI) and Water Systems Council (WSC) standard PST-2000-2005, in § 173.306(g). Currently there are 38 U.S. based manufacturers or distributors of these water pump system tanks, thus affording them certain exceptions from the regulations. PHMSA proposed to incorporate this exception in an NPRM published on July 26, 2016, titled “Hazardous Materials: Miscellaneous Amendments Pertaining to DOT-Specification Cylinders (RRR)” [81 FR 48977; HM-234]. PHMSA is looking to amend the HMR with these provisions with the publication of a final rule in 2017.

*Environmental Protection Agency*

Note: EPA's response totaled 131 pages including supporting appendices. The information below focuses only on the opportunities for streamlining permitting processes or simplifying/reducing regulations. EPA is subject to myriad and complex requirements from a variety of statutes, regulatory and permitting programs.

## **II. Opportunities to Simplify EPA's Regulatory Programs and Associated Permitting Processes**

As evidenced from Section I, EPA implements complex regulatory and permitting programs. EPA is committed to engaging in robust streamlining of its permitting regimes and reducing regulatory burdens for domestic manufacturers. While the agency has already made some improvements to its permitting processes, there are significant opportunities for reforms. Identifying and implementing those reforms will require collaboration with EPA's state and tribal partners and consultation with affected entities. Each effort will require its own set of performance metrics and outcome measures (e.g., reduced time, paperwork, duplication) in order to reduce costs and improve programmatic efficiency. Through these streamlining efforts, EPA believes the agency can create greater environmental results in the long-term and achieve the following goals:

- Speed manufacturers' "time-to-market" for new and improved products/facilities;
- Reduce the burden on manufacturer resources responding to the permitting process;
- Reduce the frequency and severity of unintended permit violations; and
- Increase clarity and consistency of interpretation and implementation surrounding permitting requirements.

EPA views the permitting process as an opportunity for continuous improvement. Its Headquarters Program Offices and its Regional Offices have begun engaging in recent years in a number of business process improvement efforts. The success of these limited efforts highlight a significant opportunity to intensify and scale up EPA's overall efforts to realize even greater benefits. A few of these efforts are described below.

### **II. A. Continuous Improvement Efforts to Streamline Permitting Processes and Minimize Regulatory Burden**

A cornerstone of EPA's improvement efforts to streamline permitting processes includes the E-Enterprise

for the Environment ePermitting and eReporting strategy. **E-Enterprise for the Environment** is a new model EPA is undertaking to bolster collaborative leadership among environmental co-regulators. Through this strategy, EPA is working with the states and tribes to simplify, streamline and modernize the implementation of the Agency's environmental permitting and reporting programs. The tools and technology available to co-regulators are enhanced by mobile applications, online portals, smart tools and other investments in information technology. Streamlining processes and using smarter tools produces improved efficiency making coregulators more productive. In turn, these productivity benefits also help regulated entities, such as those in the manufacturing sector, by reducing the time it takes to report and manage compliance. In addition to E-Enterprise, EPA has launched several specific continuous improvement efforts depicted in **Table 2** and further described below that are tailored by media, statute, and regulatory program.

**Table 2**

| <b>AIR – CAA (Title V, NSR)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
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| <b>Triage State Implementation Plans (SIPs):</b> EPA is engaged with its regional offices to reduce process steps to cut the time required to review and approve SIPs. A SIP is a state-specific federally-enforceable plan that identifies how a state will attain and/or maintain NAAQS. EPA has a backlog of nearly 700 SIPs dating back to 2013. Through an EPA LEAN event, EPA Region 7 created a SIP review process that reduces the number of steps from 165 to 134 and the number of decisions from 14 to 8. In Region 10, the SIP review process is now split in three tracks (fast, normal and high involvement), which has reduced the average process time from 19 months to 12. |
| <b>Clean Air Act:</b> Continuing its process toward finalizing the greenhouse gas significant emission rate rulemaking. EPA issued a proposed rulemaking on October 3, 2016, seeking to respond to a Supreme Court opinion and provide clarity and certainty regarding greenhouse gas emissions and Clean Air Act permitting.                                                                                                                                                                                                                                                                                                                                                                |
| <b>EPA plans to continue its process towards finalizing the Title V Petitions Rulemaking:</b> EPA issued a proposed rule on August 24, 2016 (81 FR 57822), revising its regulations to streamline and clarify processes related to the submission and review of Title V petitions that could be submitted by a petitioner to challenge a proposed Title V permit.                                                                                                                                                                                                                                                                                                                            |
| <b>Guidance on Ozone &amp; PM<sub>2.5</sub> Significant Impact Levels (SILs):</b> EPA is in the process of crafting guidance to facilitate air quality assessments involving SILs as a compliance demonstration tool. SILs                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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| that can be used as alternatives to, or in conjunction with air quality modeling, and this guidance can streamline the modeling required in the permitting process.                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Technical Guidance on Model Emissions Rates for Precursors of Ozone and Secondary PM<sub>2.5</sub>:</b><br>EPA issued draft guidance to assist state and local air agencies and manufacturing permit applicants in conducting streamlined screenings for PSD compliance with Ozone and Secondary PM <sub>2.5</sub> NAAQS that reduces the burden of PSD compliance demonstrations.                                                                                                                                                |
| <b>Data Management Tool for Permitted Emissions Limits &amp; Controls:</b> EPA maintains a “clearinghouse” documenting permit decisions, specifically related to NSR. The tool also includes information on standards such as reasonably available control technology (RACT), best available control technology (BACT), and lowest achievable emission rates (LAER). This resource can assist permit applicants by diminishing uncertainty and increasing transparency, which can advance facility’s ability to comply with permits. |
| <b>WATER – SDWA, CWA (SEC 402 [NPDES], SEC 404)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>NPDES Applications and Program Updates Rule:</b> EPA is engaged in revisions to modernize NPDES regulatory requirements consistent with CWA amendments and recent case law. Specifically, EPA’s proposed revisions would eliminate regulatory inconsistencies, improve permit documentation, enhance permit transparency, and eliminate outdated provisions.                                                                                                                                                                      |
| <b>Streamline NPDES Permit Application Forms:</b> EPA is considering streamlining the permit application process for all industrial sectors, including those required of new manufacturing facilities. Consistent with this effort, EPA is exploring options to modernize the application process, providing an online “fill-and-print” version of the forms.                                                                                                                                                                        |
| <b>NPDES Technical Assistance to Affected Manufacturing Facilities:</b> EPA is proposing to provide technical assistance to affected companies through a suite of information technology tools. The objective of these tools is to help the regulated universe quickly and efficiently identify which forms must be completed, and available resources to help in completing the forms.                                                                                                                                              |
| <b>Initiate a LEAN process for NPDES applications:</b> EPA is considering undertaking a LEAN initiative with the goal of eliminating inefficiencies in the permitting process, and minimizing duplication of effort. As part of this effort, EPA proposes to focus on developing training modules that focus on best practices for new permit applications to ensure that their NPDES application is complete and accurate, thereby avoiding unnecessary delays.                                                                     |
| <b>LAND – RCRA SUBTITLE C, TSCA</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |



**RCRA Streamlined Permit Renewal Process:** RCRA permits must be renewed every 5-10 years.

Reviewing applications and approving permits can be a lengthy process—and if the process is unclear or has too many steps it creates backlogs that can potentially slow facility operations and take too much industry and government staff time to address. EPA partnered with the State of Massachusetts to conduct a LEAN event to streamline the RCRA permit renewal process. The new process simplifies and accelerates approvals. The time to develop a draft permit for renewal was more than halved: reducing the burden on facility operators and allowing them to invest staff time in other critical tasks.

**RCRA Facilities Investigation Remedy Selection Track (RCRA FIRST):** Investigating facilities' RCRA contamination and selecting an approach to cleanup can take, on average, 16 years. Working with States and other stakeholders through a LEAN process, EPA is looking to reduce this time significantly, in some cases by more than 50 percent. EPA has started to use the RCRA FIRST to accelerate cleanup of contaminated sites and getting these sites ready for community redevelopment. RCRA FIRST is designed to save taxpayer dollars, reduce risks to human health and the environment, and expedite economic development.

**PCB Facility Approval Streamlining Toolbox (PCB FAST):** By working with stakeholders, EPA has learned about key issues that results in undue delays in PCB site cleanups. This can “mothball” properties for years – leaving them vacant and unavailable to communities for economic redevelopment. Through one regional office (in San Francisco), EPA engaged partners in LEAN business process improvement exercises to reduce the time to approve PCB cleanup applications by 20 percent through. The outcome of PCB FAST is a streamlined, standardized template for the application that is transferrable across EPA's ten regions.

3091  
3092 **II.A.1. AIR – Clean Air Act (NSR, NAAQS, PSD)**  
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3094 **State Implementation Plans (SIP)**– A SIP is a state-specific, federally-enforceable plan that identifies how  
3095 a state will attain and/or maintain the primary and secondary National Ambient Air Quality Standards  
3096 (NAAQS) under the Clean Air Act (CAA). The EPA is required to review and approve SIPs for each state  
3097 and, as of 2013, had a backlog of nearly 700 SIPs waiting to be reviewed. As of September 30, 2016, EPA  
3098 significantly reduced that backlog, but still had a backlog of 322 SIPs.  
3099

Notably, EPA Regions 7 and 10 made significant improvements to the SIP review process that drastically cut the time required to review and approve SIPs. Through EPA's LEAN government methods for identifying and eliminating waste, since 2013, EPA has reduced the backlog of SIPs waiting to be reviewed and approved by roughly 80%. Specifically, Region 7 is reducing its SIP review process steps from 165 to 134 and the numbers of decisions from 14 to 8; Region 10 is splitting its old process into three tracks (i.e. fast, normal, and high involvement), with a 36% average reduction in process time from 19 to 12 months. Along with their state partners, they eliminated steps, created standard procedures, clarified roles and responsibilities, and made many other improvements. Going forward, these improvements will allow EPA to more quickly review and approve plans, which will provide more certainty to states and local industries and better environmental protection for communities.

EPA is preparing to share these new strategies and tools Agency-wide and with states to use to eliminate steps and clarify expectations for SIP review process in the next month or so. The expedited review process provides early guidance to states on non-attainment area designations and boundaries, developing a road map for each geographic area that outlines how stakeholders can collaborate. These developed tools will: create a schedule for the SIP development and review process for all parties; triage SIPs based on difficulty of review; shift from sequential to concurrent steps at as many points as possible in the process; and engage regional planning organizations for technical work on multi-state issues.

***Title V Petitions Rulemaking*** – EPA issued a proposed rule on August 24, 2016, (see 81 FR 57822) to revise its regulations to streamline and clarify processes related to submission and review of Title V petitions. The petition process rulemaking will allow EPA to take advantage of new technology and improve transparency for our stakeholders, and to support E-enterprise, an EPA-state initiative to improve environmental performance and enhance services to the regulated community, environmental agencies, and the public.

The proposal covered five key areas, each of which should increase stakeholder access to and understanding of the petition process and aid the EPA's review of petitions. First, EPA proposed regulatory provisions that provide direction as to how petitions should be submitted to the Agency. Second, EPA proposed regulatory provisions that describe the expected format and minimum required content for Title V petitions. Third, the proposal clarified that permitting authorities are required to respond to significant

comments received during the public comment period for draft Title V permits, and to provide that response with the proposed Title V permit to EPA for the Agency's 45-day review period. Fourth, the guidance was in the form of "recommended practices" for various stakeholders to help ensure Title V permits have complete administrative records and comport with the requirements of the CAA. Fifth, this notice presented information on the Agency's interpretation of certain Title V provisions of the CAA and its implementing regulations regarding the steps following an EPA objection in response to a Title V petition. The public comment period closed on October 24, 2016. EPA plans to continue the process towards finalizing this rule.

**Guidance on Ozone and PM<sub>2.5</sub> Significant Impact Levels (SILs)** – The CAA requires that a proposed source subject to PSD permitting demonstrate that its impacts will not cause or contribute to a violation of NAAQS or PSD increments. Significant Impact Levels (SILs) are compliance demonstration tools that can be used in air quality assessments, either as alternatives to or in conjunction with air quality modeling. This draft guidance provides these tools for ozone and particulate matter (PM<sub>2.5</sub>) and a comprehensive basis for using them in making the required PSD air quality impact demonstration. Use of SILs as compliance demonstration tools can protect air quality but also streamline the air quality modeling in the permitting process for PSD sources. The guidance preserves the discretion of permitting authorities to use or not use SILs in their programs. The draft guidance is being revised according to comments received during the informal public comment period and technical peer review. EPA plans to continue the process towards finalizing this guidance.

**Technical Guidance on Developing and Use of Model Emissions Rates for Precursors (MERPs) for Ozone and Secondary PM<sub>2.5</sub>** – EPA issued this draft guidance to assist state/local air agencies and manufacturing permit applicants in conducting screening level PSD compliance demonstrations for ozone and secondary PM<sub>2.5</sub>. This guidance streamlines the permit process by providing a framework for a suitable screening approach for ozone and PM<sub>2.5</sub> along with EPA modeling data for use in conducting the assessment for PSD. The guidance streamlines and reduces burden of PSD compliance demonstrations for ozone and secondary PM<sub>2.5</sub> by providing a specific screening technique based on EPA modeling that is scientifically credible and flexible for use by permit applicants. EPA received positive public comments on this screening technique in both its proposed rulemaking to revise *Guideline on Air Quality Models* and the draft guidance document. EPA plans to continue the process towards finalizing this guidance.

**Database of Permitted Emission Limits and Controls** – The EPA has maintained a “clearinghouse” documenting permit decisions, specifically focused on NSR permits, and certain standards such as reasonably available control technology (RACT), best available control technology (BACT), and lowest achievable emission (LAER). Over the past several years, the EPA has improved the electronic platform and content contained within the RACT/BACT/LAER clearinghouse. Opportunities remain to improve both the platform and the content in a manner that would better serve as a permitting support tool for not only the regulated community, but also state/local permitting authorities. The EPA could engage in outreach with key stakeholders and identify aspects of this database that could be improved to support more streamlined and expedited New Source Review permitting.

**Outreach and Communication on Flexible Air Permitting Options** – We intend to highlight and encourage use of flexible air permitting options by developing a comprehensive website and providing communication, outreach, and training to industry and permitting authorities on this issue. This would apply to both operating and preconstruction permits. This project would educate the regulated community as well as permitting authorities about the existing streamlined, but possibly underused, permitting options. These options are particularly useful to dynamic manufacturing sectors such as the semiconductor industry and other “quick-to-market” businesses that may have changes in product lines and other changes that can impact emissions. This effort would also dovetail with other efforts seeking to improve the economic competitiveness of the U.S. manufacturing sector.

## **II.A.2. WATER – SDWA, CWA (SEC 402, SEC 404), NPDES**

**NPDES Applications and Program Updates Rule** – EPA is proposing revisions that would modernize the National Pollutant Discharge Elimination System regulations. The revisions would eliminate regulatory and application form inconsistencies; improve permit documentation, transparency and oversight; clarify existing regulations; and remove outdated provisions. The proposed revisions would provide NPDES permit writers with improved tools to write well-documented permits to protect human health and the environment. The revisions would also provide the public with enhanced opportunities for public participation in permitting actions. These revisions would further align NPDES regulations with statutory requirements from the 1987 CWA Amendments and more recent case law requirements. Potential benefits include reducing regulatory

burdens, costs, and uncertainty and increasing transparency, which can advance facility's ability to comply with permits, advancing environmental improvements, increasing production, and enhancing license to operate.

### **II.A.3 LAND – RCRA Subtitle C, TSCA**

***RCRA Streamlined Permit Renewal Process*** – EPA Region 1 and the Massachusetts Department of Environmental Protection conducted an EPA LEAN event to streamline the RCRA permit renewal process. The new process simplifies and accelerates approvals by frontloading and standardizing communications with each permittee to ensure all parties understand expectations prior to submitting the application. As a result, the number of process steps were reduced from 31 to 24, while the time required to develop a draft permit was reduced from 15 to 6.5 months. The new process includes the following key strategies and tools: meeting face to face with the permittee before initiating the renewal process; using standard communications to establish expectations and a timeline upfront; dividing sections of the permit among a team; developing a tracking sheet to keep a schedule to complete the permit in 6.5 months; and using or adapting tools from the RCRA Permitting Toolbox to improve outcomes. EPA is making these tools available Agency-wide to simplify and accelerate approvals of RCRA permits.

***RCRA Facilities Investigation Remedy Selection Track (RCRA FIRST) Toolbox*** – The process to clean up and redevelop contaminated industrial facilities involves feasibility investigation and remedy selection processes. RCRA FIRST applies business process improvements to make these processes more efficient to reduce risks and allow economic development more quickly. EPA held two LEAN events in which regional, headquarters, state, and industry representatives mapped and analyzed existing process steps. Two key root causes of delay included: 1) no common understanding by all stakeholders up front on site cleanup objectives; and 2) lack of an effective means to elevate and resolve cleanup issues. Improvements to the process were identified which are estimated to be more efficient, reduce delays, and improve communication and cleanups, in some cases reducing the length of times for key phases by up to 75%.

***PCB Facility Approval Streamlining Toolbox (PCB FAST)*** – EPA Region 9 reduced the time to approve PCB cleanup applications by 20% through an EPA LEAN business process improvement event. The improvements establish a standard template for the applications that can be used by other regions. Other

best practices identified include reaching agreement upfront on the project plan before the application is submitted; completing the site characterization before submitting an application; and incorporating routine communication early and often lead to reduced time for the review. These changes will result in improving the quality of the application, reducing delays, and strengthening relationships with state partners and the regulated industry. A description of the LEAN event and all of the tools and lessons learned is being made available Agency-wide for others to simplify and accelerate the PCB cleanup approvals.

## **II. B. Potential Improvement Efforts to Streamline Permitting Processes and Minimize Regulatory Burden for Domestic Manufacturers**

While the improvements described above are significant, the EPA acknowledges there are numerous opportunities for further reforms. Consistent with the Trump Administration's presidential memoranda and executive orders, EPA is committed to identifying additional opportunities to improve and streamline its permit processes and regulatory programs that impact the manufacturing sector. Potential new initiatives tailored by media, by statute follow. EPA expects to continue to review public comments received through its regulatory reform efforts and assess appropriate next steps for additional opportunities that may reduce burdens on domestic manufacturers.

### **II.B.1. AIR – Clean Air Act**

**Support to State and Local Air Permitting Authorities on Flexible Air Permits** - In addition to the ongoing efforts described above, the EPA could more directly engage with state and local air permitting authorities to support issuance of flexible air permits. The EPA could do this by offering support in permit reviews, supporting conversations between applicants and permitting authorities, and working collaboratively with state and local air permitting authorities.

### **II.B.2. WATER – Clean Water Act**

Under the NPDES Program, there are several streamlining opportunities that, assuming resources are available, could be undertaken to achieve efficiencies.

- EPA could streamline EPA's NPDES permit application forms for all industrial sectors, including forms required of new manufacturing facilities. This is separate from the Applications and Program Updates Rule mentioned above. EPA's Office of Water could work with stakeholders to revise its NPDES permit applications and provide modernized, online "fill-and-print" versions of the forms to streamline use by new and expanding industrial dischargers. This cleanup and streamlining effort potentially could be done without revisions to existing application regulations.

For background, new or expanding industrial and manufacturing facilities that discharge to waters of the United States, and which seek coverage under an "individual" NPDES permit, generally must submit detailed permit application forms to their federal or state permitting authority. The minimum contents of these application forms are established in federal regulations at 40 CFR 122.21. To support permit applicants, EPA developed a series of individual application forms for the various categories of applicants. While authorized state programs may develop their own application forms, many states utilize some or all of EPA's application forms.

The current EPA application forms were developed and revised at various times over the past 30 years, and EPA has noted that there are inconsistencies in the structure, appearance, and detail of instructions accompanying these forms. Both applicants and state agencies have suggested that EPA should comprehensively revise the forms to provide a consistent look and feel, as well as consistent and enhanced detail in the instructions that accompany the forms. Over the past several years, EPA has begun to address these concerns and has developed initial drafts of all of its application forms. Potential benefits include reducing paperwork burden, which can decrease time spent by facilities to complete applications, waste, uncertainty, and potential for late submittals, as well as increase the overall accuracy in data collection and aggregation that will also improve ability for facilities to benchmark their environmental performance to their peers.

- EPA's Office of Water is proposing to provide technical assistance in a variety of forms to new manufacturing facilities for NPDES training and information technology tools. First, EPA could provide enhanced web resources to guide new manufacturing facility applicants through the NPDES permit application process. EPA could do this by developing an internet-based "wizard" to

help new manufacturing facilities determine which forms are required to be filled out and to steer them in the direction of available resources to help them complete their permit applications. Potential benefits include reducing time spent by facilities to identify correct forms to be completed and by simplifying instructions for doing so, which can provide them with more time to advance environmental improvements (potentially improving compliance rates), enhance their license to operate, increase production, and respond to customer requests.

Second, EPA could provide dedicated training to new industrial facilities to reduce delays associated with incomplete or incorrectly filled out NPDES permit applications. Ensuring that the information coming is complete and accurate is a LEAN way to reduce rework. EPA could develop a dedicated training module focusing on suggested best practices for new permit applicants to ensure that their NPDES application is complete and accurate and to avoid unnecessary delays related to incorrect filings. Potential benefits include reducing time spent, waste, and cost incurred by facilities in completing permit applications, which can provide them more time to spend on value added efforts, including advancing environmental improvements, increasing production, and responding to customer requests.

## **II.C. EPA Actions Regarding Specific Regulatory Reform Targets**

EPA is committed to fulfilling the President's memorandum on permit streamlining and regulatory burden reduction for domestic manufacturers. There are actions, which EPA can take under its existing authority (without regulatory or statutory change) to streamline permitting and permit reviews. Specifically, EPA is focused on replicating and expanding prior successful LEAN business process improvement efforts and taking new actions based on the outcomes of such efforts, subject to budgetary and administration priorities.

Providing regulatory reform targets for EPA's permitting programs or regulations is neither simple nor straightforward. As previously discussed, the EPA is bound by the provisions of multiple statutes and myriad promulgated regulations supporting these statutory provisions. EPA has already taken steps to respond to several recent Executive Orders issued by the Trump Administration, including:



**Executive Order 13771** (82 FR 9339, February 3, 2017) on **Reducing Regulation and Controlling Regulatory Costs** directs federal agencies to modify or repeal two existing regulations for each new regulation proposed or finalized in fiscal year (FY) 2017 and thereafter. Subsequent Office of Management and Budget (OMB) guidance established that costs for final, significant rules in FY17 need to be fully offset by cost savings from modification or repeal of other regulations. For FY2018 and beyond, the director of OMB will provide agencies with a total amount of incremental costs that will be allowed.

**Executive Order 13777** (82 FR 12285, March 1, 2017) on **Enforcing the Regulatory Reform Agenda** directs federal agencies to designate a Regulatory Reform Officer and to establish a Regulatory Reform Task Force (Task Force). One of the duties of the Task Force is to evaluate existing regulations and make recommendations to the agency head regarding regulations that may be appropriate for repeal, replacement, or modification. The Task Force is also required to submit a progress report in mid-May, 2017.

**Executive Order 13778** (82 FR 12497, March 3, 2017) on **Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the “Waters of the United States” Rule** directs EPA to review all orders, rules, regulations, guidelines, and policies implementing or enforcing the final “Waters of the United States” Rule. Formal rulemaking procedures will follow to rescind or revise any parts of the rule.

**Executive Order 13783** (82 FR 16093, March 31, 2017) on **Promoting Energy Independence and Economic Growth** directs the EPA to review the Clean Power Plan, related rules, and New Source Performance Standards for Oil and Gas. The EO also directs agencies to review existing regulations, orders, guidance documents, and policies that potentially burden the development or use of domestically produced energy resources. Heads of agencies are required to submit a plan for the review of existing regulations to OMB by mid-May, 2017, followed by a draft report detailing actions taken under the EO by late July 2017 and a final report due in late September 2017.

EPA has taken several actions to respond to these directives. In response to EO 13777, Administrator Pruitt sent an agency-wide memorandum that announced EPA's Regulatory Task Force and designated

Samantha Dravis, Senior Counsel to the Administrator and Associate Administrator for Policy, as EPA's Regulatory Reform Officer. The Administrator's memorandum also requested multiple EPA offices to solicit input from the public on regulations that could be considered for repeal, replacement, or modification. On April 13, 2017, EPA published a *Federal Register* notice that opened a public docket for a 30-day comment period to facilitate receipt of that input. In addition, EPA offices are holding multiple meetings and teleconferences over the next three weeks to hear ideas and suggestions for regulatory reform directly from the public. Information about those meetings is available on EPA's newly launched Regulatory Reform website (<https://www.epa.gov/laws-regulations/regulatory-reform>). The information gathered at the public meetings and teleconferences, as well as the public comments provided in response to EPA's solicitation and the Department of Commerce RFI will inform the progress report required by EO 13777 that the Regulatory Reform Task Force will submit to the EPA Administrator by May 26, 2017.

In response to EOs 13778 and 13783, the EPA has already announced plans to review the Clean Water Rule, the Clean Power Plan, and related actions. In further response to EO 13783, the EPA Administrator has asked the Regulatory Reform Task Force to lead the Agency's efforts to review existing regulations that might burden the development or use of domestically produced energy resources. EPA program offices that are conducting public outreach in response to EO 13777 have been asked to look for input regarding such regulations and identify them to the Task Force. Under EO 13783, EPA has to submit a plan to the OMB Director by May 12, 2017, that proposes a plan to carry out the Agency's review of burdensome regulations on domestically produced energy. A draft report with specific recommendations is then due in late July.

EPA is taking regulatory reform very seriously, and has been proactive in soliciting input in a variety of venues that will inform multiple plans and reports that will be developed over the next few months by the Regulatory Reform Task Force in response to several Executive Orders. The regulatory programs that affect domestic manufacturers also affect other industrial sectors, and the Task Force is looking to synthesize information from multiple sources, including the Department of Commerce RFI, comments in EPA's docket, input from public meetings, and recommendations from EPA programmatic offices to inform its work over the next few months. EPA believes through these efforts, the Agency can meaningfully improve its permitting and regulatory programs to reduce burdens on domestic manufacturers, consistent with the Administration's directives.

3379 *Department of Labor*

3380 The Department is undertaking a review of its regulations in order to find ways, consistent with law, to  
3381 lessen e burdens on employers. This review is being performed in the spirit of mandates such as those  
3382 coming from Executive Order 13771. For example, Sec. 1 of Executive Order 13771 states in relevant part:  
3383 “In addition to the management of the direct expenditure of taxpayer dollars through the budgeting process,  
3384 it is essential to manage the costs associated with the governmental imposition of private expenditures  
3385 required to comply with Federal regulations.”

3386  
3387 The Department, acting consistent with the mandate of this Executive Order, is working to manage the  
3388 costs to the private sector of regulations it has promulgated. While the Department is working to reduce  
3389 regulatory burdens, it is also cognizant that certain costs are unavoidable.

3390 In a few key areas, the Department has publicly acknowledged the need for a review of its regulatory  
3391 burdens. These include those that follow.

3392

3393 Occupational Exposure to Crystalline Silica

3394 On April 6, 2017, the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA)  
3395 announced a delay in enforcement of the crystalline silica standard that applies to the construction industry  
3396 to conduct additional outreach and provide educational materials and guidance for employers.

3397 The agency has determined that additional guidance is necessary due to the unique nature of the  
3398 requirements in the construction standard. Originally scheduled to begin June 23, 2017, enforcement will  
3399 now begin Sept. 23, 2017.

3400 OSHA expects employers in the construction industry to continue to take steps either to come into  
3401 compliance with the new permissible exposure limit, or to implement specific dust controls for certain  
3402 operations as provided in Table 1 of the standard. Construction employers should also continue to prepare  
3403 to implement the standard's other requirements, including exposure assessment, medical surveillance and  
3404 employee training.

3405 Occupational Exposure to Beryllium

3406 On March 22, 2017, OSHA announced a delay in the effective date of the rule titled “Occupational  
3407 Exposure to Beryllium,” from March 21, 2017, to May 20, 2017.

3408 The delay will allow OSHA an opportunity for further review and consideration of the rule, in keeping with a  
3409 Jan. 20, 2017, White House memorandum, titled “Regulatory Freeze Pending Review.”

OSHA published the final rule on Jan. 9, 2017, and previously announced the effective date would be postponed to March 21, 2017. On March 1, 2017, OSHA sought comments on a further extension to May 20, 2017.

#### Examinations of Working Places in Metal and Nonmetal Mines

On March 24, 2017, the U.S. Department of Labor's Mine Health Safety Administration (MSHA), announced a proposed delay in the effective date of the final rule on Examinations of Working Places in Metal and Nonmetal Mines from May 23, 2017, to July 24, 2017.

MSHA proposed to delay the effective date to assure that mine operators and miners affected by the final rule have the training and compliance assistance they need.

The proposed delay is also consistent with the Jan. 20, 2017, White House memorandum, titled "Regulatory Freeze Pending Review."

MSHA published the final rule on Jan. 23, 2017. The agency is soliciting comments on the limited issue of whether to extend the effective date to July 24, 2017, and whether this extension offers an appropriate length of time for compliance.

#### Litigation on DOL Regulations

The Department is currently dealing with a number of lawsuits challenging regulations that it has promulgated through notice and comment rulemaking. In some instances, those regulations have been enjoined or held unlawful. An example is the overtime regulation from the Department's Wage and Hour Division, which has been preliminarily enjoined by a district court and is currently on appeal to the Fifth Circuit. As the Department is considering the issues, the Government has asked the court to postpone the next filing deadline until a Secretary is confirmed by the U.S. Senate. In its motion in the overtime case the Government stated:

The due date was previously extended to allow incoming leadership personnel adequate time to consider the issues. The nominee to be Secretary of Labor has not yet been confirmed. Thus, the federal government respectfully requests an additional 60-day extension, to and including Friday, June 30, 2017, for the reply brief.

#### *Federal Communications Commission*

In general, the Commission doesn't have any rules that directly relate to permits for a U.S. manufacturing plant. However, the commenters tied certain FCC regulations and permitting requirements to ancillary

manufacturing issues—primarily manufacturers’ access to communications services to improve innovation and productivity in manufacturing. The Commission agrees with commenters that over the years FCC regulation has unnecessarily hindered investment and innovation. The Commission is now undertaking a thorough review of our rules and has several proceedings underway to eliminate unnecessary regulation, including cutting through the red tape that has slowed the deployment of broadband:

1) Commission actions to reduce regulatory burdens

- a. In February 2017, the Commission granted a five-year waiver to broadband Internet access service providers with 250,000 or fewer broadband connections from the enhanced reporting requirements adopted in the 2015 Title II Order.
- b. In March 2017, the Commission took steps to reform certain outdated rules applicable to the 800 MHz Cellular Service providers, which included eliminating unnecessary rules and burdens related to application filings, domestic and international coordination, and comparative renewal.
- c. In March 2017, the Commission also took steps to streamline and eliminate certain international reporting requirements by proposing to (1) eliminate the Traffic and Revenue Reports and (2) streamline the Circuit Capacity Reports, which will lessen the regulatory requirements on international telecommunications service providers.

2) Commission actions to streamline permitting processes

- a. The Commission has started the administrative process necessary to streamline or eliminate unnecessary permitting requirements:
  - i) In December 2016, the Commission released a Public Notice that seeks comment on how the Commission could streamline and expedite the process that governs the deployment of broadband infrastructure.
  - ii) At the Commission’s April 2017 meeting, the agency plans to vote on Chairman Pai’s proposal to streamline the rules that govern the deployment of wireless broadband infrastructure. The Chairman’s plan proposes to expedite state and local approval of infrastructure deployment applications and streamline rules to advance 5G wireless broadband network deployment.

- iii) Also at the Commission’s April 2017 meeting, the agency plans to vote on Chairman Pai’s plans to streamline and facilitate the deployment of wireline broadband networks, including by asking whether the FCC should consider using its authority to preempt any unnecessary state and local regulations that are stifling broadband network deployment.

*Small Business Administration*

The Small Business Administration (SBA) does not issue rules regulating the activities of manufacturers nor does it issue permits or licenses to engage in manufacturing activity. Therefore, regulations on manufacturers that are deemed excessively burdensome will likely come from other executive agencies. SBA’s contact with manufacturers stems primarily from its loan programs, which help small businesses obtain access to capital. SBA also touches small manufacturers through its counseling and training programs. Below are brief descriptions of the programs and their relation to small manufacturers.

7(a) program. SBA’s largest loan program is the 7(a) program, which guarantees loans made from participating lenders to small businesses. The 7(a) program is open to all eligible small businesses without preferential lending terms for any particular industry.

504 program. SBA’s 504 program supports loans to small businesses for the purchase of major fixed assets. Generally, the total amount of 504 loans that may be made to each small business may not exceed \$5 million. However, small manufacturers are not subject to this \$5 million total 504 loan cap for an individual small business and may receive \$5.5 million for each eligible project. There are no preferential terms on interest rates or repayment periods.

Small Business Investment Companies (SBICs). The SBIC program does not have a statutory role in promoting or regulating manufacturing activity. SBA is currently in a “listening” and “data gathering” mode in regards to policy setting within the SBIC program. Because of the SBA’s power to license SBICs, there is some scope to express a preference for SBICs that invest in small manufacturers and this possibility is being explored.

Entrepreneurial Development programs. In FY2016, SBA’s Office of Entrepreneurial Development estimates that the agency assisted more than 20,000 small manufacturing firms with business counseling

3503 and training programs. This assistance is carried out through SBA-funded Small Business Development  
3504 Centers, Women's Business Centers, and SCORE chapters.

3505

3506

## 3507 Appendix 5 – Regulatory Reform Efforts Grouped by Reform Category

3508

## 3509 A. Analysis Best Practices.

| Reform                                                          | Description                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1981-- EO 12291<br>(Reagan)                                     | Many sources credit this EO with first establishing the cost-benefit analysis requirement.                                                                                                                                                                                                                                                                                                                                |
| 1993—EO 12866<br>(Clinton)                                      | Requires agencies to: assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating; include quantifiable and qualitative costs and benefits; select approaches that maximize net benefits in choosing among alternative regulatory approaches; impose the least burden on society...including the costs of cumulative regulations; consider incentives for innovation. |
| 1995- Title II of the<br>Unfunded Mandates<br>Reform Act (UMRA) | Requires qualitative and quantitative assessment of anticipated costs and benefits when a rule costs more than \$100 million annually; does not apply to independent regulatory agencies <sup>123</sup> ; Agencies must consider a reasonable number of alternatives and select the least costly, most cost-effective, or least burdensome. <sup>124</sup>                                                                |
| 2001- Information<br>Quality Act aka Data<br>Quality Act        | Amended the Paperwork Reduction Act; Agencies must maximize the quality, objectivity, utility, and integrity of information (including statistical information) disseminated. <sup>125</sup>                                                                                                                                                                                                                              |
| 2003 - OMB Circular A-<br>4, Regulatory Analysis                | OMB and the Council of Economic Advisors guidance on regulatory analysis, refining and replacing the 1996 best practices document. <sup>126</sup>                                                                                                                                                                                                                                                                         |
| 2007 –EO 13422 (Bush<br>43)                                     | Amended EO 12866, including the requirements that agencies identify the market failure that the regulation addresses and that they include an estimate of cumulative costs for all regulations planned for that calendar year.                                                                                                                                                                                            |
| 2009 – EO 13497<br>(Obama)                                      | Revoked EO 13422; restoring EO 12866 as written                                                                                                                                                                                                                                                                                                                                                                           |

<sup>123</sup> Maeve P. Carey, "Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register", Congressional Research Service, October 4, 2016

<sup>124</sup> Maeve P. Carey (coordinator), "The Federal Rulemaking Process: An Overview", Congressional Research Service, June 17, 2013

<sup>125</sup> CRS, "Federal Regulatory Reform"

<sup>126</sup> CRS, "Federal Regulatory Reform"



|                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2011 – EO 13563<br>(Obama) | Regulation must be based on best available science; identify and use the best, most innovative, and least burdensome tools; include consideration of cumulative costs; must offer benefits that justify costs; identify and assess alternatives (including economic incentives), select the approach that maximizes net benefits; maintain flexibility and freedom of choice; use the best available techniques to quantify costs and benefits; ensure the objectivity of any scientific and technological information and processes; be designed to promote innovation |
| 2011 - EO 13579<br>(Obama) | Encourages independent regulatory agencies to follow guidelines set out in EO 13563.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

3510

3511 *B. Retrospective Review/Regulatory Look-back.*

| Reform                                                               | Description                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1979 - EO 12044<br>(Carter)                                          | Section 4: Agencies shall periodically review their existing regulations to determine whether they are achieving the policy goals of this Order                                                                                                                                                                                                                                                     |
| 1980 - Regulatory Flexibility Act (RFA)                              | Section 610 requires agencies to review rules that have or will have a significant impact on small entities within 10 years of their promulgation to determine whether they should be continued without change or should be amended or rescinded to minimize their impact. <sup>127</sup>                                                                                                           |
| 1992- Memorandum on Reducing the Burden of Govt Regulation (Bush 41) | Asked agencies to evaluate existing regulations and programs and to identify and accelerate action on initiatives that will eliminate unnecessary burden                                                                                                                                                                                                                                            |
| 1993 - EO 12866<br>(Clinton)                                         | Section 5: Requires agencies to “periodically review” existing regulations for modification or elimination. Agencies must look for regulations that “have become unjustified or unnecessary”; confirm that regulations are “compatible with each other and not duplicative or inappropriately burdensome in the aggregate”; and must “otherwise improve the effectiveness of existing regulations.” |

<sup>127</sup> CRS, “Federal Rulemaking Process”

|                            |                                                                                                                                                                                                                                                          |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2011 - EO 13563<br>(Obama) | Section 6- Retrospective Analyses of Existing Rules – institutionalizes a process for retrospective review by agencies                                                                                                                                   |
| 2011 - EO 13579<br>(Obama) | Encourages independent regulatory agencies to develop and make public plans for retrospective review of their regulations. <sup>128</sup>                                                                                                                |
| 2012 - EO 13610<br>(Obama) | Emphasizes the importance of public participation in the retrospective review process, sets a schedule for agencies' retrospective review status reports, and sets the President's priorities for the identification of rules for review. <sup>129</sup> |

3512

3513 *C. Establishing Oversight/Watchdog Organizations and Defining Roles.*

| Reform                                | Description                                                                                                                                                                                              |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1980- Paperwork Reduction Act (PRA)   | Established OIRA as part of OMB to review collections of information from the public, review draft regulations under EO 12866, and oversee agency implementation of the Data Quality Act. <sup>130</sup> |
| 1980-Regulatory Flexibility Act (RFA) | Section 612 requires the SBA to monitor and report at least annually on agencies' compliance with RFA. <sup>131</sup>                                                                                    |
| 1981- EO 12291<br>(Reagan)            | Requires OIRA review of regulations and accompanying Regulatory Impact Assessment (RIA). <sup>132</sup>                                                                                                  |
| 1981- Task Force on Regulatory Relief | Created by Reagan Administration to review pending regulations, study past regulations with an eye toward revising them, and recommend appropriate legislative remedies. <sup>133</sup>                  |
| 1985- EO 12498<br>(Reagan)            | Extended OIRA's influence requiring agencies to submit a regulatory program to OMB for review each year that covered all of their significant regulatory actions underway or planned. <sup>134</sup>     |

<sup>128</sup> GWU, "EPA's Retrospective Review"<sup>129</sup> GWU, "EPA's Retrospective Review"<sup>130</sup> NERA/MAPI, "Macroeconomic Impacts"<sup>131</sup> CRS, "Federal Rulemaking Process"<sup>132</sup> RFF, "Grading Estimates"<sup>133</sup> CRS, "Federal Regulatory Reform"<sup>134</sup> CRS, "Federal Regulatory Reform"

|                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1989- President's Council on Competitiveness                           | Established by Bush 41 to review regulations that would have a significant impact on the economy or particular industries. <sup>135</sup>                                                                                                                                                                                                                                                                                                                    |
| 1993- Clinton EO 12866                                                 | Abolished President's Council on Competitiveness and redefined OIRA (limited its scope to "significant" rules and required it to complete reviews in 90 days in order to eliminate the bottleneck it was creating in the rulemaking process). <sup>136</sup>                                                                                                                                                                                                 |
| 1995- Natl Partnership for Reinventing Govt                            | Under VP Gore, undertook major reform of the U.S. regulatory system. <sup>137</sup>                                                                                                                                                                                                                                                                                                                                                                          |
| 1995- Title II of the Unfunded Mandates Reform Act (UMRA)              | Requires Cabinet departments and independent agencies (but not independent regulatory agencies) to prepare a written statement on the cost and benefits of major rules (annual economic impact of \$100 million). <u>OIRA is responsible for monitoring compliance</u> and publishes annually the <i>OMB Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities</i> . <sup>138</sup> |
| 1996- Congressional Review Act (CRA)                                   | Established expedited procedures by which Congress may disapprove agencies' rules; Before any final rule can become effective it must be filed with each house of Congress and GAO including a copy of any cost-benefit analysis prepared for the rule and a report on the agency's actions related to any relevant act or executive order. <sup>139</sup>                                                                                                   |
| 2001- Regulatory Right-to-Know Act aka General Govt Appropriations Act | Requires OMB to prepare and submit a report containing an estimate of the total costs and benefits (including quantifiable and non-quantifiable effects) of federal rules. This annual report is combined with UMRA requirements into the OMB report described under UMRA above. <sup>140</sup>                                                                                                                                                              |

3514

3515 *D. Public Engagement; Transparency.*

| Reform | Description |
|--------|-------------|
|--------|-------------|

<sup>135</sup> CRS, "Federal Regulatory Reform"<sup>136</sup> CRS, "Federal Regulatory Reform"<sup>137</sup> Mercatus, 2012-0418, *The Role of Retrospective Analysis and Review in Regulatory Policy*<sup>138</sup> CRS, "Federal Rulemaking Process"<sup>139</sup> CRS, "Federal Rulemaking Process"<sup>140</sup> CRS, "Federal Rulemaking Process"

|                                             |                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1935- Federal Register Act                  | Established the Federal Register and Code of Federal Regulations (CFR) for a single Federal Government regulations and public review system                                                                                                                                                                                                                       |
| 1946- Administrative Procedure Act (APA)    | Requires that agencies publish a notice of proposed rulemaking (NPRM) in the Federal Register... giving interested persons an opportunity to comment on the proposed rule. Also requires that public comments be made available for public inspection. <sup>141</sup>                                                                                             |
| 1980-Regulatory Flexibility Act (RFA)       | Section 602 requires each agency to publish in the Federal Register a listing of regulations that will be proposed that are likely to impact small entities; also ensures that small entities have an opportunity to participate in the rulemaking process, with special requirements for EPA, OSHA, and the Consumer Financial Protection Bureau. <sup>142</sup> |
| 1993- Clinton EO 12866                      | Requires information provided to the public be in “plain, understandable language” and requires OIRA to convene conferences with representatives of businesses, NGOs, and the public “to discuss regulatory issues of common concern.”                                                                                                                            |
| 1996- Negotiated Rulemaking Act             | Encourages agencies to work with interest groups that would be affected by a regulation to address areas of concern. <sup>143</sup>                                                                                                                                                                                                                               |
| 1998- Govt Paperwork Elimination Act (GPEA) | Requires that federal agencies provide the public electronic (versus paper) options for information maintenance, submission, or disclosure. <sup>144</sup>                                                                                                                                                                                                        |
| 2002- E-Government Act                      | Requires agencies to accept public comments electronically and to make all comments publically viewable on a federal website. <sup>145</sup>                                                                                                                                                                                                                      |
| 2011 – Obama EO 13563                       | Requires that regulations promote predictability and reduce uncertainty; Regulatory process must involve public participation including an open exchange of information and perspectives, which includes agencies providing online access to relevant scientific and technical findings.                                                                          |
| 2011 - Obama EO 13579                       | Encourages independent regulatory agencies to follow guidelines set out in EO 13563.                                                                                                                                                                                                                                                                              |

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<sup>141</sup> CRS, “Federal Rulemaking Process”

<sup>142</sup> CRS, “Federal Rulemaking Process”

<sup>143</sup> CRS, “Federal Rulemaking Process”

<sup>144</sup> CRS, “Federal Rulemaking Process”

<sup>145</sup> CRS, “Federal Regulatory Reform”

3516

3517 *E. Reduce Waste and Inefficiency in General.*

| Reform                                                                    | Description                                                                                                                                                                                                                                                                    |
|---------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1980 Paperwork Reduction Act (PRA)                                        | Established to minimize the paperwork burden resulting from the collection of information by or for the federal government; agencies must receive OIRA approval for each collection. <sup>146</sup>                                                                            |
| 1993—Clinton EO 12866                                                     | Requires agencies to avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies                                                                                                                       |
| 1995- Natl Partnership for Reinventing Govt (aka Natl Performance Review) | Under VP Gore, Phase II of this effort focused on reducing regulatory burdens, ultimately identifying 16,000 pages of the Federal Register for elimination. <sup>147</sup>                                                                                                     |
| 2004- OMB initiative to reform regulation of US manufacturing sector      | OMB requested public nominations of specific regulations, that, if reformed, could result in lower costs, greater effectiveness, enhanced competitiveness, more regulatory certainty and increased flexibility. <sup>148</sup>                                                 |
| 2011- Obama EO 13563                                                      | Section 3: Encourages agencies to coordinate and harmonize with other agencies to reduce redundancy, inconsistency, and overlapping regulations.                                                                                                                               |
| 2011- Obama Memorandum- Administrative Flexibility                        | Instructs OMB and agencies to work with State, local, and tribal governments to identify and eliminate “unnecessary administrative, regulatory, and legislative burdens”, including “unnecessary, unduly burdensome, duplicative, or low-priority recordkeeping requirements.” |

3518

3519 *F. Special Consideration for Small Businesses.*

| Reform | Description |
|--------|-------------|
|--------|-------------|

<sup>146</sup> CRS, “Federal Rulemaking Process”<sup>147</sup> [govinfo.library.unt.edu/npr/whowere/history2.html](http://govinfo.library.unt.edu/npr/whowere/history2.html)<sup>148</sup> OMB/OIRA, “Regulatory Reform”

|                                                                   |                                                                                                                                                                                                                                                                                                                          |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1980-Regulatory Flexibility Act (RFA)                             | Requires agencies to assess the impact of regulations on “small entities” if the regulation will have “significant economic impact on a substantial number of small entities”. <sup>149</sup>                                                                                                                            |
| 1980 Paperwork Reduction Act (PRA)                                | One of the purposes of the PRA is to minimize the paperwork burden for small businesses. <sup>150</sup>                                                                                                                                                                                                                  |
| 1993- Clinton EO 12866                                            | “Each agency shall tailor its regulations to impose the least burden on society, including ... businesses of differing sizes...” Also requires the “development of short forms and other streamlined regulatory approaches for small businesses...”                                                                      |
| 1996- Small Business Regulatory Enforcement Fairness Act (SBREFA) | RFA amendment -- permits judicial review of agencies’ compliance with initial and final regulatory flexibility analysis requirements, etc.; also imposes new rulemaking-related requirements related to small businesses. <sup>151</sup>                                                                                 |
| 2003- Small Business Paperwork Relief Act                         | Amended the PRA to, among other things, require each agency to establish a small business liaison with regard to information collection and paperwork issues [and] directed agencies to make a special effort to reduce information collection burdens for small businesses with fewer than 25 employees. <sup>152</sup> |
| 2003- Bush 43 EO 13272                                            | Requires agencies to “assess and take appropriate account” of the impact of their rules on small businesses.                                                                                                                                                                                                             |

3520

3521 *G. Permitting.*

| Reform                                                                                                                              | Description                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| 2011- Obama Memorandum-Speeding Infrastructure Development through More Efficient and Effective Permitting and Environmental Review | Instructs agencies to identify and work to expedite permitting and environmental reviews for high-priority infrastructure projects |

<sup>149</sup> CRS, “Federal Rulemaking Process”<sup>150</sup> CRS, “Federal Rulemaking Process”<sup>151</sup> CRS, “Federal Rulemaking Process”<sup>152</sup> CRS, “Federal Rulemaking Process”

|                                                                                                                    |                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2012- Obama EO 13604                                                                                               | Established guidelines to improve permitting and review of infrastructure projects by the federal government, including encouraging early collaboration and consultation among agencies and other stakeholders to “avoid conflicts or duplication of effort, resolve concerns, and allow for concurrent rather than sequential reviews.” |
| 2015 FAST-41 (Fixing America’s Surface Transportation Act)                                                         | Codifies many previously identified best practices for Federal permitting, such as assignment of a lead coordinating agency for a project and the use of coordinated project plans, resulting in benefits such as enhanced coordination, increased visibility and predictability, and public participation. <sup>153</sup>               |
| 2015- Red Book aka <i>Synchronizing Environmental Reviews for Transportation and Other Infrastructure Projects</i> | DOT, U.S. Army Corps of Engineers, EPA and several other agencies updated this handbook, which provides processes for interagency synchronization of permitting schedules. <sup>154</sup>                                                                                                                                                |

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<sup>153</sup> FPISC Best Practices- FINAL 01182017

<sup>154</sup> FPISC Best Practices- FINAL 01182017

## 3524 Appendix 6 – Abbreviations Used in References to RFI Responses

3525

| RFI # | Abbreviation        | Respondent                                                                                                                                                             |
|-------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6     | NFIB                | Nat'l Federation of Independent Business                                                                                                                               |
| 10    | PA                  | Pennsylvania Chamber of Business and Industry                                                                                                                          |
| 39    | IPC                 | Association Connecting Electronics Industries                                                                                                                          |
| 43    | Mosaic              | Mosaic Fertilizer                                                                                                                                                      |
| 48    | RFF                 | Resources for the Future                                                                                                                                               |
| 51    | NSSGA               | National Stone, Sand and Gravel Association                                                                                                                            |
| 53    | ACMA                | American Composites Manufacturers Association                                                                                                                          |
| 63    | CRN                 | Council for Responsible Nutrition                                                                                                                                      |
| 67    | AHFA                | Am. Home Furnishings Alliance, Kitchen Cabinet Intl. Assoc., Intl Wood Prods Assocs., Rec. Vehicle Ind. Assoc., Natl Retail Federation, Retail Industry Leaders Assoc. |
| 70    | GMA                 | Grocery Manufacturers Association                                                                                                                                      |
| 74    | Knouse              | Knouse Foods Cooperative Inc.                                                                                                                                          |
| 75    | SLMA                | Southeastern Lumber Manufacturers Association                                                                                                                          |
| 76    | Boeing              | Boeing                                                                                                                                                                 |
| 79    | Northrup<br>Grumman | Northrop Grumman Corporation                                                                                                                                           |
| 84    | Ameren              | Ameren Corp                                                                                                                                                            |
| 86    | IPAA                | Independent Petroleum Association of America                                                                                                                           |
| 89    | IECA                | Industrial Energy Consumers of America                                                                                                                                 |
| 92    | AISI                | American Iron and Steel Institute                                                                                                                                      |
| 98    | IDFA                | International Dairy Foods Association                                                                                                                                  |
| 101   | AA                  | Aluminum Association                                                                                                                                                   |
| 107   | COC                 | US Chamber of Commerce                                                                                                                                                 |
| 109   | Valero              | Valero Companies                                                                                                                                                       |
| 112   | SMA                 | Steel Manufacturers Association; Specialty Steel Industry of North America                                                                                             |
| 114   | AGC                 | Associated General Contractors of America                                                                                                                              |



|     |          |                                                                                |
|-----|----------|--------------------------------------------------------------------------------|
| 120 | NTMA/PMA | National Tooling and Machining Association; Precision Metalforming Association |
| 122 | AHPA     | American Herbal Products Association                                           |
| 123 | 3M       | 3M                                                                             |
| 126 | API      | American Petroleum Institute                                                   |
| 128 | Pugh     | Theresa Pugh Consulting                                                        |
| 133 | PIA      | Plastics Industry Association                                                  |
| 136 | AFPM     | American Fuel & Petrochemical Manufacturers                                    |
| 137 | MEMA     | Motor & Equipment Manufacturers Association                                    |
| 144 | AFPA     | American Forest & Paper Association                                            |
| 146 | NAM      | National Association of Manufacturers                                          |
| 147 | US Steel | United States Steel Corporation                                                |
| 152 | AWC      | American Wood Council                                                          |
| 155 | PMPA     | Precision Machined Products Association                                        |
| 158 | CKRC     | Cement Kiln Recycling Coalition                                                |
| 170 | APF      | Air Permitting Forum                                                           |

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3529 **Appendix 7 – Matrix of Respondents.**

3530 *Insert link.*

3531

## **Desk Statement**

### **EPA Spring 2017 Semi-annual Regulatory Agenda**

EPA's 2017 Semi-annual Regulatory Agenda reflects the Trump Administration's commitment to refocusing the agency on our core mission of protecting the nation's air, water and land and reducing regulatory burden. With a significant reduction in the number of regulations planned, it shows the agency will pursue sensible actions that protect health and the environment, while also promoting economic growth.

#### **Background**

As required by EO 12866, EPA's 2017 Semiannual Regulatory Agenda was released as part of the government-wide Unified Agenda. It describes EPA regulations that are under development or review, and that are expected to be signed by the EPA Administrator. Rules may be regulatory or deregulatory.

EPA's 2017 Regulatory Agenda includes 95 active actions (e.g., actions with a projected stage within the next 12 months), 62 long-term actions, 41 actions that have been issued, and 22 actions that have been withdrawn since the publication of the fall 2016 Semiannual Agenda. It also includes a new subset of X rules that are inactive.

Among the actions in the latest Regulatory agenda:

- 66 actions are appearing for the first time; of those X are deregulatory and X are inactive.
- 12 actions are estimated to be economically significant (having an economic impact of \$100 million or more); of those X are deregulatory and X are inactive.

All EPA rules are subject to detailed review and evaluation before they are issued. For a number of reasons, some rules on the list of active actions may never be issued.

EPA will publish its next Semi-annual Regulatory Agenda and Regulatory Plan in Fall 2017.

To access EPA's 2017 Spring Semi-Annual Regulatory Agenda, go to: <https://www.epa.gov/laws-regulations/regulatory-agendas-and-regulatory-plans>.

**To:** Bolen, Brittany[bolen.brittany@epa.gov]  
**Cc:** Kime, Robin[Kime.Robin@epa.gov]  
**From:** Rees, Sarah  
**Sent:** Tue 7/18/2017 9:10:29 PM  
**Subject:** Reg Reform Stakeholder Meetings\_talking points\_June 2017.docx  
Reg Reform Stakeholder Meetings\_talking points\_June 2017.docx

Hi Brittany – attached are reg reform talking points for Thursday's SLC meeting. Let me know if you need anything else.

Cheers,

Sarah

**To:** Rees, Sarah[rees.sarah@epa.gov]; Laws-Regs[Laws-Regs@epa.gov]  
**Cc:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]; Brown, Byron[brown.byron@epa.gov]; Shea, Quin[QShea@eei.org]; Fisher, Emily[EFisher@eei.org]; Steckelberg, Kathy[KSteckelberg@eei.org]; Chuck Barlow - Entergy Corporation (cbarlow@entergy.com)[cbarlow@entergy.com]  
**From:** Bond, Alex  
**Sent:** Mon 5/15/2017 7:57:47 PM  
**Subject:** Comments of the Edison Electric Institute  
[EEIComment DocketID EPAHQQA20170190.pdf](#)

Dear Ms. Rees:

The Edison Electric Institute appreciates the opportunity to provide input on the Environmental Protection Agency's notice—in accordance with Executive Order (E.O.) 13777, Enforcing the Regulatory Reform Agenda—seeking comments on regulations that may be appropriate for repeal, replacement or modification. Our comments are attached here, and have also been submitted to the docket. Thank you!

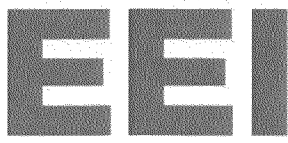
--

Alex Bond

Associate General Counsel, Energy & Environment  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2696  
202-508-5523  
[www.eei.org](http://www.eei.org)

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**Edison Electric  
INSTITUTE**

**Quinlan J. Shea, III**  
Vice President, Environment

May 15, 2017

Sarah Rees  
U.S. Environmental Protection Agency  
Office of Regulatory Policy and Management  
1200 Pennsylvania Avenue, N.W.  
Mail Code 1803A  
Washington, D.C. 20460

[Submitted Electronically]

RE: Docket ID No. EPA-HQ-OA-2017-0190; Evaluation of Existing Regulations

Dear Ms. Rees:

The Edison Electric Institute (EEI) appreciates the opportunity to provide input on the Environmental Protection Agency's (EPA's or Agency's) notice—in accordance with Executive Order (E.O.) 13777, Enforcing the Regulatory Reform Agenda—seeking comments on regulations that may be appropriate for repeal, replacement or modification. The identification of these regulations is likewise consistent with the requirements of E.O. 13771, Reducing Regulation and Controlling Regulatory Costs, which stipulates that two regulations be identified for elimination or revision for every new regulation proposed and that the costs of regulations be managed and controlled via a budgeting process.

EEI is the association that represents all U.S. investor-owned electric companies. Our members provide electricity for 220 million Americans and operate in all 50 states and the District of Columbia. As a whole, our industry supports more than 7 million American jobs. Safe, reliable, affordable and clean energy powers the economy and enhances the lives of all Americans.

Driven by customer demands, technology developments, and federal and state regulatory obligations, the electric sector is undergoing a transition of its generating fleet that will continue over the next decade and beyond. Concurrent with this transition, EEI member companies are investing significant amounts of capital to make the energy grid smarter, more dynamic, more flexible, and more secure in order to integrate and deliver a balanced mix of resources from both central and distributed energy resources to customers.

The power sector has significantly decreased its emissions. At the end of 2016, the sector's emissions of sulfur dioxide (SO<sub>2</sub>) were down 53 percent since 2014 and 91 percent from 1990 levels; emissions of nitrogen oxides (NO<sub>x</sub>) were down by 28 percent and 82 percent, respectively over the same periods. Additionally, carbon dioxide (CO<sub>2</sub>) emissions were nearly 25 percent below 2005 levels. This has all occurred while electricity demand has increased 36 percent since 1990.

To support the ongoing fleet transformation and facilitate the continued operation of electric generating units (EGUs), EEI supports cost-effective public policies and a streamlined approach to regulation. In particular, EEI continues to support efforts—administratively and legislatively—to reform the permitting and siting process for critical energy infrastructure projects. An efficient and expeditious permitting process will enable electric companies to invest in energy infrastructure projects that will benefit customers, achieve greater environmental benefits, create jobs, and stimulate the economy.

EPA efforts to evaluate existing and forthcoming regulations and to look for areas of potential improvement are a key step toward establishing a regulatory structure that can appropriately support and inform the types of long-term investments EEI's members make in both existing and new generation capacity, as well as electric transmission lines and natural gas infrastructure. Consistent with EPA's request and E.O. 13777, these comments focus on examples of EPA regulations and significant guidance documents that potentially could be revised in order to reduce administrative burdens, simplify and streamline the overall process, and enhance the ability of EEI's members to permit, site and operate generation, transmission and other infrastructure assets while maintaining environmental integrity.

Importantly, these comments specifically do not address wider regulatory initiatives already identified by the Administration—including, but not limited to, the Administration's stated intent to revise the Waters of the United States (WOTUS) rule; E.O. 13783, Promoting Energy Independence and Economic Growth, which requires a review and possible revision, rescission or replacement of the Clean Power Plan; the reconsideration of the effluent limitations guidelines and standards for the steam electric point source category; and, any changes to regional haze requirements. EEI and its members intend to participate in these initiatives as they are developed.

### **The Clean Air Act (CAA)**

Many of EEI members' generation and other assets are subject to numerous requirements under the CAA and, in particular, are subject to requirements for individual source permitting. Briefly and non-exhaustively, EGUs often must obtain individual source permits as part of the State Implementation Plan (SIP) process to help attain and maintain the National Ambient Air Quality Standards (NAAQS) under CAA section 110, which includes permitting under the Prevention of Significant Deterioration (PSD) program contained across CAA sections 160-169. Further, fossil fuel-based EGUs are subject to New Source Performance Standards (NSPS) under CAA section 111, and have fully implemented standards to reduce emissions of hazardous air pollutants (HAPs) under CAA section 112. Fossil fuel-based EGUs also comply with requirements under Title

IV's Acid Rain Program, obtain operating permits consistent with Title V of the CAA, and address visibility concerns under CAA section 169A.

EEL's members aim to comply with this array of requirements in a coordinated and cost-effective fashion so that they can continue to provide safe, reliable and affordable electricity to customers.

Certain elements of these regulatory programs could be streamlined, improved or modified in order to reduce the administrative burdens these programs can impose, thereby reducing costs to customers while maintaining or exceeding current levels of environmental protection. Such changes would enhance the ability of EEL's members to permit, site and operate fossil fuel-based generation, transmission, and other infrastructure assets while also protecting the environment. To that end, EPA should:

- Modify the Greenhouse Gas Reporting Rule to incentivize the deployment of carbon capture and storage (CCS) technology by clarifying that CO<sub>2</sub> utilized for enhanced oil recovery (EOR) should not report under Subpart RR, but instead under Subpart UU. Such a change would help to incentivize, and make more cost effective, the deployment of CCS technologies by allowing the captured CO<sub>2</sub> to be utilized more widely for EOR;
- Evaluate stack testing and reporting requirements—which exist across multiple rules and programs—to streamline compliance requirements. Numerous programs under CAA sections 112 and 110, as well as requirements for compliance with CAA title IV and title V, require duplicative stack testing and emissions reporting. In addition, EPA should evaluate whether the frequency of testing that is currently required is necessary given the widespread use of Continuous Emissions Monitoring Systems (CEMS) by EGUs, and should evaluate whether the emissions reports required under current programs are duplicative of the reports contained within a unit's title V operating permit;
- Withdraw the “once in, always in” guidance that interprets certain CAA section 112 applicability requirements so that a major source will always be treated as major, even if it becomes an area source under EPA's regulation. Reinterpreting this guidance could encourage fossil fuel-based EGUs to make improvements that would reduce emissions if they would allow reclassification as a minor source, with the attendant reductions in reporting obligations;
- Reevaluate the final rule establishing operational and emission controls for units identified as commercial and industrial solid waste incineration (CISWI) units, which establishes standards on units that “combust[s] any solid waste.”



Historically, however, several types of materials have been introduced into utility boilers, including boiler cleaning waste and refined coal, as a practical way to manage material without increasing emissions and to reduce the emissions of certain contaminants. These beneficial practices should not trigger CISWI regulation, within the boundaries established by court precedent. The evaporation of boiler cleaning waste in utility boilers is a practical, cost-effective method for managing materials that are mostly or entirely water-based and does not increase emissions beyond regulatory thresholds. Accordingly, EPA should clarify the CISWI rule to explain that these activities do not necessarily trigger regulation, and allow fossil fuel-based EGU operators to manage waste materials and emissions in a cost-effective manner, subject to environmental considerations.

#### **The Resource Conservation and Recovery Act (RCRA)**

Many of EEI's members also are regulated under RCRA through the provisions of EPA's Coal Combustion Residuals (CCR) rule. While the CCR rule provides significant health protections and requirements for appropriately managing CCRs, the Water Infrastructure Improvement for the Nation (WIIN) Act provides a mechanism for implementation of the CCR rule through state or federal permit programs and therefore the rule should be revised to allow regulatory agencies to tailor the rule's groundwater monitoring and corrective action programs based on site-specific conditions while maintaining the rule's important environmental protections. This would reduce both administrative and substantive economic burdens on fossil fuel-based EGU operators. EPA should:

- Extend compliance dates established in the CCR rule to provide time for implementation of permit programs given the WIIN Act's establishment of procedures for states and EPA to implement the CCR rule through permit programs. This will avoid unnecessary capital expenditures for elements of the rule that may be implemented differently by a state permit program than as contemplated by EPA's final CCR rule;
- Revise the CCR rule to include site-specific flexibility regarding groundwater monitoring and corrective action similar to that provided in the municipal solid waste regulations and applied under state risk-based cleanup programs;
- Modify the CCR rule so that inactive surface impoundments (*i.e.*, impoundments that did not receive CCR after the rule's effective date) are not subject to regulation. EPA and the states can address any risks from these units in a more cost-effective manner under pre-existing imminent hazard provisions.

#### **The Clean Water Act (CWA)**

EEI's members are subject to numerous requirements under the CWA because some of the activities undertaken by electric utilities result in a discharge of pollutants to—or a modification of—a WOTUS, therefore requiring a permit under the CWA. Specifically,

EEI's members often must comply with the requirements of section 402, the National Pollutant Discharge Elimination System (NPDES), and section 404, Permits for Dredged or Fill Material that include the streamlined Nationwide Permits (NWP) program. EGUs also are governed by a variety of other substantive CWA provisions that address water quality criteria and standards, including cooling water intake structures through CWA section 316(b) and effluent guidelines.

EEI's members strive to comply with this array of requirements in a coordinated and cost-effective fashion. However, certain parts of EPA's regulatory programs under the CWA could be streamlined, improved or modified to help reduce the administrative burdens these programs can impose, thereby reducing costs to customers while protecting the environment. To that end, EPA should:

- Withdraw the 2015 Water Quality Standard rule, which impinges on states' authority to set water quality standards while considering each state's priorities and greatly reduces state flexibility to consider other factors when establishing standards. The rule unnecessarily complicates the process and could hamper the ability of fossil fuel-based EGUs to obtain and comply with NPDES permits;
- Rescind EPA's 2016 human health criteria for Washington state and Maine and reinstate the prior practice of giving states discretion as to how they apply fish consumption and exposure criteria by allowing them to propose more applicable criteria. Allowing the states to propose their own criteria potentially save significant project implementation costs;
- Withdraw the proposed 2016 NPDES Application and Program Updates rule, which would make changes to the state-delegated NPDES program and establish federal veto authority, among other concerning programmatic changes. The proposed rule has the potential to create additional permit backlogs, and EEI looks forward to engaging in a constructive dialogue with the Agency to explore opportunities for achieving additional efficiencies in the NPDES program;
- Withdraw the final 2016 EPA-USGS report, "Protecting Aquatic Life from Effects of Hydrologic Alteration." The report addresses protections for aquatic life from the effects of flow alteration—in particular, for changes in historic flow patterns that can result from climate change. However, the final report did not address all the technical and policy concerns raised by commenters;
- Withdraw the proposed "Draft Field-based Methods for Developing Aquatic Life Criteria for Specific Conductivity" given the document's technical and scientific deficiencies that would generate overly conservative criteria, leading to unnecessarily costly implementation of water quality criteria.

Again, EEI appreciates the opportunity to provide input on the EPA's notice requesting comment in accordance with E.O. 13771. If you have any questions concerning EEI's input, please contact me ([qshea@eei.org](mailto:qshea@eei.org) or 202-508-5027) or another member of the EEI team.

Sincerely,

A handwritten signature in black ink, appearing to read 'QJ Shea III', with a long horizontal flourish extending to the right.

Quinlan J. Shea, III

cc: Ryan Jackson  
Samantha Dravis  
Brittany Bolen  
Byron Brown  
Mandy Gunasekara  
Emily Fisher  
Kathy Steckelberg  
Chuck Barlow

**To:** William Lovell (lovell.william@epa.gov)[lovell.william@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Mon 12/4/2017 11:48:44 PM  
**Subject:** FW:  
EPA Spring 2017 Reg Agenda-7.19.2017.docx

Hi Will - I'm reviewing the agenda handout and per my handwritten note I am recirculating this email with my revised version of the handout for the spring agenda.

-----Original Message-----

From: Bolen, Brittany  
Sent: Wednesday, July 19, 2017 7:08 PM  
To: Bowman, Liz <Bowman.Liz@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
Cc: Brown, Byron <brown.byron@epa.gov>; Samantha Dravis (dravis.samantha@epa.gov) <dravis.samantha@epa.gov>  
Subject: RE:

Sorry for delay on this, folks. Samantha and I had a lot of back-and-forth with OMB on the agenda the last 24 hours. Attached is the updated one-pager with the suggested desk statement. Let us know if you have any questions.

-----Original Message-----

From: Bowman, Liz  
Sent: Tuesday, July 18, 2017 2:37 PM  
To: Jackson, Ryan <jackson.ryan@epa.gov>  
Cc: Brown, Byron <brown.byron@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>  
Subject: Re:

Can you all provide me more information?

Sent from my iPhone

> On Jul 18, 2017, at 2:35 PM, Jackson, Ryan <jackson.ryan@epa.gov> wrote:  
>  
> The Unified Regulatory Agenda will be announced Thursday. I wanted to ensure we are plugged in  
> press and OP wise.  
>  
> \_\_\_\_\_  
> Ryan Jackson  
> Chief of Staff  
> U.S. EPA  
> (202) 564-6999

**To:** Abboud, Michael[abboud.michael@epa.gov]  
**Cc:** Letendre, Daisy[letendre.daisy@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Thur 7/20/2017 3:12:35 PM  
**Subject:** Updated one-pager  
EPA Spring 2017 Reg Agenda-7.20.2017.docx

**Brittany Bolen**

Deputy Associate Administrator, Office of Policy  
U.S. Environmental Protection Agency  
(202) 564-3291  
Bolen.Brittany@epa.gov

**To:** Dravis, Samantha[dravis.samantha@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Thur 7/20/2017 3:11:53 PM  
**Subject:** RE: You want to send Anthony this?  
[EPA Spring 2017 Reg Agenda-7.20.2017.docx](#)

Hey, did you end up sending this doc? Bridgid just sent me an updated figure. Please use the attached.

---

**From:** Dravis, Samantha  
**Sent:** Wednesday, July 19, 2017 8:38 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Subject:** Re: You want to send Anthony this?

Yes thanks!

Sent from my iPad

On Jul 19, 2017, at 7:10 PM, Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)> wrote:

Anthony – As discussed on the phone earlier, attached is the one-pager we provided our OPA team on the agenda. Let us know if you have any questions. Thanks.

<EPA Spring 2017 Reg Agenda-7.19.2017.docx>

**To:** Lovell, William[lovell.william@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Fri 6/16/2017 12:05:52 PM  
**Subject:** Re: For your review by tomorrow 12:00 a.m. please: Responds to QFRs from May 19 House E&C drinking water hearing

Thanks will. I sent edits back.

Sent from my iPhone

On Jun 16, 2017, at 8:04 AM, Lovell, William <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)> wrote:

Wanted to make sure you remembered to look at these – deadline is noon today.

---

**From:** Kime, Robin  
**Sent:** Thursday, June 15, 2017 8:06 AM  
**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Cc:** Lovell, William <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)>  
**Subject:** For your review by tomorrow 12:00 a.m. please: Responds to QFRs from May 19 House E&C drinking water hearing

Good morning,  
OCIR received a set of Questions for the Record from a May 19 House Energy & Commerce drinking water hearing. We sent in a [statement for the record](#) for that hearing in lieu of a witness, and we offered to take QFRs. The QFRs have arrived. OCIR asks that we submit answers to the two questions below. Sarah and Bill drafted these answers below. With your edits, I'll share them with OCIR by their deadline of noon tomorrow. Thanks and have a good day.

**6. What steps has EPA taken to implement President Trump's Executive Order on Reducing Regulation and Controlling Regulatory Costs?**

**Deliberative Process / Ex. 5**

**a. How is EPA choosing which two regulations to repeal for every new regulation promulgated?**

**Deliberative Process / Ex. 5**

**Cc:** Dravis, Samantha[dravis.samantha@epa.gov]  
**To:** Lovell, Will (William)[lovell.william@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Tue 7/25/2017 10:03:55 PM  
**Subject:** Please print this  
M-17-24.pdf  
ATT00001.txt

**EOP / Ex. 6**



**To:** Kime, Robin[Kime.Robin@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Tue 6/20/2017 11:46:00 AM  
**Subject:** Can you plz print 3 copies of this?  
Accomplishments - 6.5.2017.docx  
ATT00001.txt

**To:** Letendre, Daisy[[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)]  
**From:** Bolen, Brittany  
**Sent:** Tue 6/27/2017 2:18:03 PM  
**Subject:** Fwd: Administrator's accomplishments  
[Accomplishments - 6.20.2017.docx](#)  
[ATT00001.htm](#)

Sent from my iPhone

Begin forwarded message:

**From:** "Bolen, Brittany" <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Date:** June 20, 2017 at 7:00:16 PM EDT  
**To:** "Greaves, Holly" <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>  
**Cc:** "Liz Bowman ([bowman.liz@epa.gov](mailto:bowman.liz@epa.gov))" <[bowman.liz@epa.gov](mailto:bowman.liz@epa.gov)>, "Samantha Dravis ([dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov))" <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** RE: Administrator's accomplishments

Update attached. This will need updated before Tuesday in order to account for finalizing the TSCA framework rules and likely WOTUS next Monday.

---

**From:** Greaves, Holly  
**Sent:** Tuesday, June 20, 2017 12:53 PM  
**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Subject:** RE: Administrator's accomplishments

Thank you!

---

**From:** Bolen, Brittany  
**Sent:** Tuesday, June 20, 2017 11:01 AM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>  
**Cc:** Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>  
**Subject:** Re: Administrator's accomplishments

Ladies, the accomplishments need just the edits I sent in my separate email with the last draft. I will do it. Just got out of a 10am meeting. Standby.

Sent from my iPhone

On Jun 20, 2017, at 10:33 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

I wouldn't stress about getting this today or tomorrow b/c Personal Matters / Ex. 6 and tomorrow in NYC...unless you want him to review it on the train, which actually might be good.

---

**From:** Greaves, Holly  
**Sent:** Tuesday, June 20, 2017 10:12 AM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>  
**Subject:** RE: Administrator's accomplishments

Gotcha – I am going to see if we can get the binder to him today for the SAC hearing. If the accomplishments are not ready until Thursday morning (as we have hearing prep scheduled), that is fine.

---

**From:** Bowman, Liz  
**Sent:** Tuesday, June 20, 2017 10:03 AM  
**To:** Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>

ED\_002158A\_00005481-00001

**Subject:** RE: Administrator's accomplishments

What time? We are in New York until like 8 p.m. tomorrow night

---

**From:** Greaves, Holly

**Sent:** Monday, June 19, 2017 10:06 PM

**To:** Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>

**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>

**Subject:** RE: Administrator's accomplishments

Thanks, yes, that is great - we are giving him an updated binder on Wednesday evening. Thanks!

---

**From:** Bolen, Brittany

**Sent:** Monday, June 19, 2017 9:55 PM

**To:** Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)>

**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>

**Subject:** Re: Administrator's accomplishments

Hi there,

I do not, but I can update it. Tomorrow afternoon work?

Brittany

Sent from my iPhone

On Jun 19, 2017, at 9:51 PM, Greaves, Holly <[greaves.holly@epa.gov](mailto:greaves.holly@epa.gov)> wrote:

Brittany/Liz,

The last version of the Administrator's Accomplishments I have is dated June 5<sup>th</sup>. Do either of you have an updated version for hearing prep?

Thanks,  
Holly

**To:** Brown, Byron[brown.byron@epa.gov]  
**From:** Bennett, Tate  
**Sent:** Mon 6/26/2017 9:09:54 PM  
**Subject:** Fwd: Guidance for Rural Prosperity Task Force Workgroup Meetings  
[AGRPTF Workgroup Guidance 6 29 17.docx](#)  
[ATT00001.htm](#)

Begin forwarded message:

**From:** SM.OSEC.RURALPROSPERITY <[RURALPROSPERITY@OSEC.USDA.GOV](mailto:RURALPROSPERITY@OSEC.USDA.GOV)>  
**Date:** June 26, 2017 at 4:55:42 PM EDT  
**To:** "Page, Tim A. - NRCS, Washington, DC" <[Tim.Page@wdc.usda.gov](mailto:Tim.Page@wdc.usda.gov)>, "Shuford, Campbell - OSEC, Washington, DC" <[Campbell.Shuford@osec.usda.gov](mailto:Campbell.Shuford@osec.usda.gov)>  
**Subject:** **Guidance for Rural Prosperity Task Force Workgroup Meetings**

Hello all,

Please read the attached document in advance of our first Rural Prosperity Task Force Workgroup meetings on Thursday, June 29<sup>th</sup> at the U.S. Department of Agriculture.

Please let us know if you have any questions.

Thank you.

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

**To:** Rees, Sarah[rees.sarah@epa.gov]; Laws-Regs[Laws-Regs@epa.gov]  
**Cc:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]; Brown, Byron[brown.byron@epa.gov]; Shea, Quin[QShea@eei.org]; Fisher, Emily[EFisher@eei.org]; Steckelberg, Kathy[KSteckelberg@eei.org]; Chuck Barlow - Entergy Corporation (cbarlow@entergy.com)[cbarlow@entergy.com]  
**From:** Bond, Alex  
**Sent:** Mon 5/15/2017 7:57:47 PM  
**Subject:** Comments of the Edison Electric Institute  
[EEIComment DocketID EPAHQQA20170190.pdf](#)

Dear Ms. Rees:

The Edison Electric Institute appreciates the opportunity to provide input on the Environmental Protection Agency’s notice—in accordance with Executive Order (E.O.) 13777, Enforcing the Regulatory Reform Agenda—seeking comments on regulations that may be appropriate for repeal, replacement or modification. Our comments are attached here, and have also been submitted to the docket. Thank you!

--

Alex Bond

Associate General Counsel, Energy & Environment  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2696  
202-508-5523  
[www.eei.org](http://www.eei.org)

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**To:** 2017HQfirstassistants[2017HQfirstassistants@epa.gov]; 2017Regionfirstassistants[2017Regionfirstassistants@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]; Bennett, Tate[Bennett.Tate@epa.gov]; Brown, Byron[brown.byron@epa.gov]; Davis, Patrick[davis.patrick@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]; Flynn, Mike[Flynn.Mike@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]; Knapp, Kristien[Knapp.Kristien@epa.gov]; Threet, Derek[Threet.Derek@epa.gov]; Burden, Susan[Burden.Susan@epa.gov]; Wagner, Kenneth[wagner.kenneth@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Schwab, Justin[schwab.justin@epa.gov]; Hupp, Millan[hupp.millan@epa.gov]; Bowman, Liz[Bowman.Liz@epa.gov]; Fonseca, Silvina[Fonseca.Silvina@epa.gov]; Allen, Reginald[Allen.Reginald@epa.gov]; Reeder, John[Reeder.John@epa.gov]; Baptist, Erik[baptist.erik@epa.gov]; Darwin, Henry[darwin.henry@epa.gov]; Darwin, Veronica[darwin.veronica@epa.gov]; Kelly, Albert[kelly.albert@epa.gov]; Falvo, Nicholas[falvo.nicholas@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]  
**From:** Knapp, Kristien  
**Sent:** Fri 7/21/2017 9:12:21 PM  
**Subject:** Weekly Report - July 21, 2017  
[EPA Weekly Report July 21 2017.docx](#)

Good afternoon,

Attached is the weekly report for July 21, 2017.

Thanks,  
Kristien

Kristien Knapp  
Special Assistant (OAR, OITA, OGC, OP)  
Office of the Administrator  
(202) 564-3277

**To:** Brown, Byron[brown.byron@epa.gov]  
**From:** Bennett, Tate  
**Sent:** Thur 6/29/2017 4:27:28 PM  
**Subject:** Fwd: Guidance for Rural Prosperity Task Force Workgroup Meetings  
[AGRPTF Workgroup Guidance 6 29 17.docx](#)  
[ATT00001.htm](#)

Found this in my spam.

Begin forwarded message:

**From:** SM.OSEC.RURALPROSPERITY <[RURALPROSPERITY@OSEC.USDA.GOV](mailto:RURALPROSPERITY@OSEC.USDA.GOV)>  
**Date:** June 26, 2017 at 4:55:42 PM EDT  
**To:** "Page, Tim A. - NRCS, Washington, DC" <[Tim.Page@wdc.usda.gov](mailto:Tim.Page@wdc.usda.gov)>, "Shuford, Campbell - OSEC, Washington, DC" <[Campbell.Shuford@osec.usda.gov](mailto:Campbell.Shuford@osec.usda.gov)>  
**Subject:** **Guidance for Rural Prosperity Task Force Workgroup Meetings**

Hello all,

Please read the attached document in advance of our first Rural Prosperity Task Force Workgroup meetings on Thursday, June 29<sup>th</sup> at the U.S. Department of Agriculture.

Please let us know if you have any questions.

Thank you.

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.

**To:** Dravis, Samantha[dravis.samantha@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]  
**Cc:** Pitsor, Kyle[Kyle.Pitsor@Nema.org]; Kohorst, Mark[Mar\_Kohorst@nema.org]  
**From:** Thompson, Letitia  
**Sent:** Mon 7/24/2017 8:51:34 PM  
**Subject:** NEMA Comments - RE: Regulatory Reform Actions at U.S. EPA  
NEMA letter to EPA on reg review - REVISED july 2017.pdf

July 24, 2017

Ms. Samantha K. Dravis  
Regulatory Reform Officer  
Associate Administrator, Office of Policy  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

**RE: Regulatory Reform Actions at U.S. EPA**

Dear Ms. Dravis:

On behalf of Kyle Pitsor, Vice President of Government Relations, I am hereby submitting a revised version of NEMA comments regarding the Environmental Protection Agency's Regulatory Reform efforts, which we originally transmitted to your office on June 9<sup>th</sup>. We contacted your office last week and indicated our intent to modify our initial comments and Chief of Staff Robin Kime advised us to transmit the revised document in this manner. Please substitute the attached statement for the version currently in the docket.

If you have any questions on these comments, please contact Mark Kohorst of NEMA at 703-841-3249 or Mar\_Kohorst@nema.org.

Very truly yours,

Letitia Thompson  
Government Relations  
NEMA – National Electrical Manufacturers Association  
1300 North 17<sup>th</sup> Street, Suite 900  
Rosslyn, VA 22209

P: 703.841.3240  
F: 703.841.3340  
E: let\_thompson@nema.org

---

NEMA's 91st Annual Membership Meeting  
Bonita Springs, Florida  
November 8-9  
REGISTER TODAY! <http://www.nema.org/annual-meeting>





**KYLE PITSOR**

Vice President, Government Relations

July 24, 2017

Ms. Samantha K. Dravis  
Regulatory Reform Officer  
Associate Administrator, Office of Policy  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

**RE: Regulatory Reform Actions at U.S. EPA**

Dear Ms. Dravis:

The National Electrical Manufacturers Association (NEMA) is the primary trade association representing the interests of the US electrical products industry. Our nearly 350 member companies manufacture products used in the generation, transmission, distribution, control, and end-use of electricity, constituting the very foundation of the worldwide infrastructure for supplying power.

This letter is offered in response to the President's expressed priority of reducing regulatory burdens affecting the U.S. manufacturing sector. The President created a framework for regulatory reform through a series of memoranda and Executive Orders<sup>1</sup> and the administration has solicited public input on rules and regulations that warrant evaluation. NEMA has two recommendations in this regard and we are pleased to submit them for your consideration. They are described below.

**1. The Significant New Alternatives Policy (SNAP) Program**

Housed within the Strategic Protection Division of EPA's Office of Air and Radiation, the SNAP program reviews environmentally preferable substitutes for ozone depleting chemicals (ODCs) in industrial product sectors. This includes products designed for "Fire Suppression and Explosion Protection," which are manufactured by NEMA members.

The SNAP program was created under Subchapter VI of the Clean Air Act Amendments of 1990 entitled "Stratospheric Ozone Depletion." It was devised as a means to

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<sup>1</sup> E.g., White House memorandum re: "Regulatory Freeze Pending Review," January 20, 2017; Presidential Memorandum re: "Streamlining Permitting and Reducing Regulatory Burdens for Domestic Manufacturing," January 24, 2017; Presidential Executive Order on Reducing Regulation and Controlling Costs, January 30, 2017; Presidential Executive Order on Enforcing the Regulatory Reform Agenda; Presidential Executive Order on Promoting Energy Independence and Economic Growth, March 28, 2017

National Electrical Manufacturers Association  
1300 North 17th Street, Suite 900 - Rosslyn, VA 22209

evaluate alternatives to ODCs, which at the time were being phased out to slow deterioration of the ozone layer.

In recent years, United Nations scientists (and others) have determined that the ozone layer is steadily recovering to benchmark 1980 levels.<sup>2</sup> Much of the progress stems from control measures adopted under the Montreal Protocol on Substances that Deplete the Ozone Layer, which has been universally ratified and came into effect January 1, 1989.

We have heard from NEMA members who have characterized the SNAP chemical submission process as an expensive, lengthy and unpredictable ordeal that acts as an impediment to achieving third-party certification for products intended to rely on substitute chemicals. They have been frustrated by continual requests for additional information from SNAP program staff, whose inquiries at times suggest a lack of technical proficiency.

For these reasons, NEMA respectfully suggests that the agency conduct a review of the submission process with a view to changes that would reduce processing time, improve predictability, and reduce costs for evaluating Fire Suppression and Explosion Protection products. Ideally, this effort will lead to internal process modifications that will lessen the burden on manufacturers.

## **2. Stormwater Runoff Requirements under NPDES Permits**

Under Title III of the Clean Water Act, EPA uses National Pollution Discharge Elimination System (NPDES) permits as the vehicle for implementing stormwater runoff controls at construction sites as well as production facilities in designated industrial sectors. One of these sectors - Light Manufacturing - encompasses "*electronic and other electrical equipment manufacturing*," which broadly intersects with NEMA's product scope.

NEMA recognizes the importance of stormwater management systems in preventing "non-point source" discharge of pollutants to our nation's navigable waters. Invariably, however, Stormwater Pollution Prevention Plans (SWPPPs) implemented through general or site-specific permits have the effect of "consuming" acreage at a site and thereby reducing the amount of land available for productive uses.

It is critical that Best Management Practices prescribed in SWPPPs for production facilities achieve sufficient, measurable benefits in terms of reducing runoff and preventing pollution. NEMA members question whether existing permit regulations and approval procedures are adequately aligned with this objective. Otherwise, land set aside for treatment systems, erosion control berms, buffer zones, sediment ponds, and other management practices can limit the economic development potential of industrial sites. This can have a detrimental impact not only on the companies affected but also on surrounding communities.

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<sup>2</sup> <https://www.sciencedaily.com/releases/2014/09/140910162324.htm>

Given the nationwide scope of this issue and the inherent challenges of effective stormwater control, we recommend that EPA initiate a review of the impact of the NPDES stormwater discharge program on manufacturing sites.

NEMA would welcome discussing these programs and others in more detail with you and your staff. In the meantime we are happy to provide more information or answer any questions you have about the electrical product industry, our members, and their experience with federal regulatory compliance. Feel free to contact Mark Kohorst of NEMA Government Relations at your convenience at 703-841-3249 or [mar\\_kohorst@nema.org](mailto:mar_kohorst@nema.org).

Very truly yours,

A handwritten signature in black ink that reads "Kyle Pitsor". The signature is written in a cursive, flowing style.

Kyle Pitsor  
Vice President, Government Relations

**To:** Dravis, Samantha[dravis.samantha@epa.gov]  
**Cc:** Lopez, George[lopez.george@epa.gov]; Daisy Letendre[Personal Email / Ex. 6]  
**From:** Lovell, Will (William)  
**Sent:** Wed 6/28/2017 7:46:33 PM  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management  
Draft 3.docx

This draft does not incorporate any edits from Daisy.

Daisy, please find attached a third draft of the AWMA article. Please let me know if you have any edits I can incorporate. Thanks.

---

**From:** Dravis, Samantha  
**Sent:** Wednesday, June 28, 2017 3:43 PM  
**To:** Lovell, Will (William) <lovell.william@epa.gov>  
**Cc:** Lopez, George <lopez.george@epa.gov>; Daisy Letendre [Personal Email / Ex. 6]  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management

Has Daisy worked on this and are her edits incorporated into this draft?

---

**From:** Lovell, William  
**Sent:** Wednesday, June 28, 2017 2:12 PM  
**To:** Dravis, Samantha <dravis.samantha@epa.gov>  
**Cc:** Lopez, George <lopez.george@epa.gov>  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management

Samantha,

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Best,  
Will

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Please let us know how else we can help with this project. I will check my work phone this weekend in case you would like something done quickly.

Best,  
Will

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**Sent:** Friday, June 16, 2017 8:20 AM  
**To:** Lovell, William <lovell.william@epa.gov>  
**Subject:** FW: Gentle reminder on the article of EPA priorities in air and waste management

Will,

Can you give this a shot to start putting together an outline for this article? Use the report we recently did for the Administrator on

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**From:** John Bachmann [mailto: ] **Ex. 6**  
**Sent:** Friday, June 16, 2017 7:23 AM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Gentle reminder on the article of EPA priorities in air and waste management

Hi Samantha,

Just a note to remind you that we are shooting for the end of June for your draft article.

Again, thank you so much for this important contribution to this issue.

John Bachmann

On May 24, 2017, at 10:44 AM, Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)> wrote:

Thanks, John. I haven't yet had a chance to start this, but could still try to get you something by the end of June if that is the time frame.

---

**From:** John Bachmann [mailto: ] **Ex. 6**  
**Sent:** Wednesday, May 24, 2017 10:42 AM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Re: Request for an article of EPA priorities in air and waste management

Hi Samantha,

I'm just checking in to see where things stand on an article. Again, thanks for your consideration

John Bachmann

On May 2, 2017, at 11:38 AM, Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)> wrote:

Thank you for the request, John. Let me run the traps internally and see if I can write something up for you.

---

**From:** John Bachmann [mailto: ] **Ex. 6**  
**Sent:** Tuesday, May 02, 2017 10:58 AM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Request for an article of EPA priorities in air and waste management

I am writing on behalf of the Air and Waste Management Association (<https://www.awma.org>), whose members consist of environmental professionals from various industries, consultants, state, local, and federal agencies, and academics. We publish a monthly e-magazine called EM, which is targeted towards environmental managers from these groups. Our September issue of EM will consist of stakeholders perspectives on the most important air and waste related management priorities for the new Administration. As is our custom for special stakeholder issues like this, we would welcome a lead article from the Environmental Protection Agency. We are also reaching out to stakeholders representing various industries, states, environmentalists, and academics.

In soliciting an EPA article for one of our stakeholder comment issues of EM, we usually work through the air or waste EPA program offices. In this search, as the head of the policy office, you were recommended as the best contact for this request. Some specifics. We are looking for an article of 2000 to 3000 words in length that focuses on EPA's priorities, particularly for air and

waste management. You are free to go beyond those areas, and it could be authored by you or anyone you believe would be an appropriate to represent EPA's perspectives. We are asking authors to provide a near final draft by the end of June, but can be somewhat flexible as the normal review process does not apply for policy related opinion pieces. You would have a chance to review the galley proofs of the article before it goes to publication.

I hope you will consider our request as an opportunity to communicate directly with our members. If you have any questions in making a decision, please let me know. I'm available either through this email or by phone at 919 619-0769.

Thank you for your consideration.

John Bachmann  
Vision Air Consulting, LLC  
EM Editorial Board

**To:** Dravis, Samantha[dravis.samantha@epa.gov]  
**Cc:** Lopez, George[lopez.george@epa.gov]  
**From:** Lovell, William  
**Sent:** Wed 6/28/2017 6:11:44 PM  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management  
Draft 3.docx

Samantha,

Please find attached a third draft for the AWMA article.

Best,  
Will

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**To:** Lovell, William <lovell.william@epa.gov>  
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**Personal Email / Ex. 6**

Robin should have copies!

**Personal Email / Ex. 6**

---

**From:** John Bachmann [mailto: ] **Personal Email / Ex. 6**  
**Sent:** Friday, June 16, 2017 7:23 AM  
**To:** Dravis, Samantha <dravis.samantha@epa.gov>  
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**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
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Thank you for your consideration.

John Bachmann  
Vision Air Consulting, LLC  
EM Editorial Board



**To:** Dravis, Samantha[dravis.samantha@epa.gov]  
**From:** Bowman, Liz  
**Sent:** Wed 6/28/2017 2:54:20 PM  
**Subject:** RE:  
[Accomplishments - 6.20.2017.docx](#)

Attached

---

**From:** Dravis, Samantha  
**Sent:** Wednesday, June 28, 2017 10:54 AM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>  
**Subject:**

Hey, can I have the latest list of "EPA accomplishments" or whatever we've been pushing out on that front? I will explain.

**To:** Dravis, Samantha[dravis.samantha@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Wed 7/19/2017 11:10:34 PM  
**Subject:** You want to send Anthony this?  
[EPA Spring 2017 Reg Agenda-7.19.2017.docx](#)

Anthony – As discussed on the phone earlier, attached is the one-pager we provided our OPA team on the agenda. Let us know if you have any questions. Thanks.

**To:** Lovell, Will (William)[[lovell.william@epa.gov](mailto:lovell.william@epa.gov)]; Lopez, George[[lopez.george@epa.gov](mailto:lopez.george@epa.gov)]; Dravis, Samantha[[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)]  
**From:** Letendre, Daisy  
**Sent:** Thur 6/29/2017 6:11:48 PM  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management  
[Draft 3 DCL Edits.docx](#)

My edit attached.

---

**From:** Letendre, Daisy  
**Sent:** Wednesday, June 28, 2017 5:07 PM  
**To:** Lovell, William <[lovell.william@epa.gov](mailto:lovell.william@epa.gov)>; Lopez, George <[lopez.george@epa.gov](mailto:lopez.george@epa.gov)>; Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** RE: Gentle reminder on the article of EPA priorities in air and waste management

Just looping in on this email. I am working on this now and will have it final tomorrow.

---

**From:** Lovell, Will (William)  
**Sent:** Wednesday, June 28, 2017 4:15 PM  
**To:** Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>  
**Subject:** FW: Gentle reminder on the article of EPA priorities in air and waste management

---

**From:** Lovell, Will (William)  
**Sent:** Wednesday, June 28, 2017 3:47 PM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Cc:** Lopez, George <[lopez.george@epa.gov](mailto:lopez.george@epa.gov)>; Daisy Letendre <**Personal Email / Ex. 6**>  
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**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Request for an article of EPA priorities in air and waste management

I am writing on behalf of the Air and Waste Management Association (<https://www.awma.org>), whose members consist of environmental professionals from various industries, consultants, state, local, and federal agencies, and academics. We publish a monthly e-magazine called EM, which is targeted towards environmental managers from these groups. Our September issue of EM will consist of stakeholders perspectives on the most important air and waste related management priorities for the new Administration. As is our custom for special stakeholder issues like this, we would welcome a lead article from the Environmental Protection Agency. We are also reaching out to stakeholders representing various industries, states, environmentalists, and academics.

In soliciting an EPA article for one of our stakeholder comment issues of EM, we usually work through the air or waste EPA program offices. In this search, as the head of the policy office, you were recommended as the best contact for this request. Some specifics. We are looking for an article of 2000 to 3000 words in length that focuses on EPA's priorities, particularly for air and waste management. You are free to go beyond those areas, and it could be authored by you or anyone you believe would be an appropriate to represent EPA's perspectives. We are asking authors to provide a near final draft by the end of June, but can be somewhat flexible as the normal review process does not apply for policy related opinion pieces. You would have a chance to review the galley proofs of the article before it goes to publication.

I hope you will consider our request as an opportunity to communicate directly with our members. If you have any questions in making a decision, please let me know. I'm available either through this email or by phone at 919 619-0769.

Thank you for your consideration.

John Bachmann  
Vision Air Consulting, LLC  
EM Editorial Board

**To:** Dravis, Samantha[dravis.samantha@epa.gov]; Bolen, Brittany[bolen.brittany@epa.gov]  
**From:** Lovell, William  
**Sent:** Tue 6/20/2017 11:25:37 PM  
**Subject:** ISRI Materials  
[170621 ISRI BP.docx](#)  
[Recycling Fact Sheet.pdf](#)  
[Reg Reform Comment.pdf](#)  
[Updated Reg Reform TPs.docx](#)

Please find attached the materials for tomorrow's meeting with **ISRI**.  
I will insert these materials into your schedules.

**Will Lovell**

Policy Assistant, Office of Policy  
U.S. Environmental Protection Agency  
(202) 564-5713  
[Lovell.William@epa.gov](mailto:Lovell.William@epa.gov)

## **Briefing Paper**

**Meeting:** Institute of Scrap Recycling Industries

**Date:** Wednesday, June 21, 2017

**Time:** 10:00 – 10:30 am

**Location:** ISRI's Offices (1250 H Street, NW, Suite 400)

**POC:** William H. Johnson, Chief Lobbyist, Institute of Scrap Recycling Industries; direct - (202) 662-8548, cell - (202) 714-4259

---

### **Participants**

- Jay Robinovitz, President & CEO, Alter Trading
- Michael Goldstein, Operations, Alter Trading
- K. Denise Rucker Krepp, Government Relations Counsel, EMR USA
- Brian Halloran, Director of Recycling, Commercial Metals Company Americas
- Hidemi Takani, General Manager, Ferrous Raw Materials Division, Mitsui Steel
- Masaya Inamuro, Senior Vice President of the Mineral & Metal Resources Division, Mitsui Steel
- George Adams, CEO, SA Recycling
- Galdino Claro, CEO, Sims Metal Management
- William "Bill" Schmiedel, President, Sims Metal Management
- Mark Lewon, President and ISRI Chair, Utah Metal Works
- Haley Barbour, Founding Partner, BGR Group

### **Purpose**

To discuss regulatory reform.

### **Institute of Scrap Recycling Industries**

ISRI is the trade association representing companies that process, broker, and consume scrap commodities, including metals, paper, plastics, glass, rubber, electronics, and textiles. It has 21 chapters nationwide and represents more than 1,200 companies operating in nearly 3,000 locations in the U.S. and 34 countries worldwide.

### **Comments**

*Docket: EPA-HQ-OA-2017-0190*

*Title: Evaluation of Existing Regulations*

*Status: Proposed Rule (April 13, 2017)*

#### **1. Definition of Solid Waste**

On December 10, 2014, the EPA finalized the "Definition of Solid Waste" rule. The rule went into effect on July 13, 2015. Previously, a 2008 rule excluded recycled materials from the definition of solid waste, exempting the materials from certain RCRA regulations. The new rule provides that exception only in certain circumstances, such as in the case of domestic and processed materials.

ISRI advocates that this rule adds unnecessary regulatory burden on the scrap recycling industry. ISRI supports revising this rule to deregulate scrap commodities and provide guidance to regional EPA offices and states.

## 2. Federal Multi-Sector General Permit (40 CFR 122)

The Federal Multi-Sector General Permit (MSGP) requires that facilities implement best management practices (BMPs) to stay below stormwater benchmark concentration levels. If a benchmark level is exceeded, facilities must review their BMPs and determine if additional BMPs must be implemented, or if other corrective measures are needed.

ISRI advocates that the stormwater benchmark concentration levels were set unrealistically low. While exceeding these levels is not a permit violation, it exposes the industry to frivolous and expensive lawsuits. ISRI supports raising the stormwater benchmark concentration levels.

## 3. Refrigerant Management Regulations (40 CFR 82 Subpart F)

Section 608(b)(1) of the Clean Air Act requires the EPA to promulgate regulations mandating that all CFC refrigerants be removed from every appliance, machine, or other good prior to its disposal or delivery for recycling. Current rules, however, place the responsibility for removing the refrigerant on the recycler.

ISRI advocates that this rule places an unnecessary liability, compliance, and enforcement burden on recyclers. ISRI supports requiring prior removal of refrigerant delivered for recycling.

## 4. Chemical Data Reporting (40 CFR 711)

From 1986 to 2003, TSCA Chemical Data Reporting (CDR) did not apply to inorganic chemical substances (e.g., scrap metal). The 2003 TSCA CDR Amendments changed that by adding every metal element to the TSCA Chemical Substance Inventory. Since the CDR definition of “manufacture” includes importing more than 12.5 tons every year, scrap recyclers became chemical manufacturers subject to reporting requirements.

ISRI advocates that such reporting is burdensome and provides no useful information to the EPA. ISRI supports eliminating the reporting requirements for scrap metal imported to be recycled.

## 5. Regulatory Conflicts

EPA regulations often conflict with each other. For instance, the word “disposal” is defined differently in different parts of the Code of Federal Regulations. Additionally, regulations affecting refrigerant management and the venting of hydrocarbons (e.g., propane) conflict with each other.

ISRI supports the Office of Policy coordinating across program offices to avoid regulatory conflicts and difficulties in current and previous rules.



**To:** John Bachmann  
**From:** Dravis, Samantha  
**Sent:** Fri 6/30/2017 9:57:07 PM  
**Subject:** RE: Request for an article of EPA priorities in air and waste management  
Draft 3 DCL Edits (002).docx

I can continue working on this, but here's where we're at.

---

**From:** John Bachmann [mailto: ] **Personal Email / Ex. 6**  
**Sent:** Friday, June 30, 2017 5:04 PM  
**To:** Dravis, Samantha <dravis.samantha@epa.gov>  
**Subject:** Re: Request for an article of EPA priorities in air and waste management

Hi Samantha,

I thought I'd let you know several other authors have not turned in their drafts as yet - and the EM editor won't be back in the office until Wednesday morning, the 5th. Even though it's not that much help at this point given the holiday, there is no need to turn in anything until July 5th.

Again, thanks.

On Jun 25, 2017, at 7:32 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

John,

I realized I read the email wrong! I'm so sorry. I thought the email was meant to be cross at me that I had not responded. Still drinking from a fire hose and apparently too busy to properly read my emails :)

I have a draft of the article but it needs work and has to go through internal reviews, so I really am looking at the VERY end of June to be able to flip something back to you - is that going to work?

I am so sorry again for the confusion on my end!!

Samantha

Sent from my iPad

On Jun 21, 2017, at 5:08 PM, [ ] **Personal Email / Ex. 6** wrote:

My number is 919 619-0769

I am sorry to offend you, which is the last thing I wanted to do. I absolutely understand how busy you have to be right now.

Sent from my iPad

On Jun 21, 2017, at 4:33 PM, Dravis, Samantha <dravis.samantha@epa.gov> wrote:

Give me your phone number, please.

Your email about throwing in a gratuitous comment re: Notre Dame is utterly absurd. We were working on this this week. As you can imagine, I have MANY competing priorities at the moment.

Sent from my iPhone

On Jun 21, 2017, at 4:26 PM, John Bachmann < [ ] **Personal Email / Ex. 6** wrote:

Hi Samantha,

I wonder if the email I sent back in May responding to this got lost -

The end of June is the timeframe and I was very happy you were able to do it. I also threw in a gratuitous comment about me going to the 2017 Reunion at Notre Dame, where I understand you went to law school.

In any event, I hope it's still possible for you to provide a brief summary of EPA's priorities, particularly for air and/or waste.

Thanks.

John Bachmann

On May 24, 2017, at 10:44 AM, Dravis, Samantha  
<[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)> wrote:

Thanks, John. I haven't yet had a chance to start this, but could still try to get you something by the end of June if that is the time frame.

---

**From:** John Bachmann [mailto:Personal Email / Ex. 6]  
**Sent:** Wednesday, May 24, 2017 10:42 AM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Re: Request for an article of EPA priorities in air and waste management

Hi Samantha,

I'm just checking in to see where things stand on an article.  
Again, thanks for your consideration

John Bachmann

On May 2, 2017, at 11:38 AM, Dravis, Samantha  
<[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)> wrote:

Thank you for the request, John. Let me run the traps internally and see if I can write something up for you.

---

**From:** John Bachmann  
[mailto:Personal Email / Ex. 6]  
**Sent:** Tuesday, May 02, 2017 10:58 AM  
**To:** Dravis, Samantha <[dravis.samantha@epa.gov](mailto:dravis.samantha@epa.gov)>  
**Subject:** Request for an article of EPA priorities in air and waste management

I am writing on behalf of the Air and Waste Management Association (<https://www.awma.org>), whose members consist of environmental professionals from various industries, consultants, state, local, and federal agencies, and academics. We publish a monthly e-magazine called EM, which is targeted towards environmental managers from these groups. Our September issue of EM will consist of stakeholders perspectives on the

most important air and waste related management priorities for the new Administration. As is our custom for special stakeholder issues like this, we would welcome a lead article from the Environmental Protection Agency. We are also reaching out to stakeholders representing various industries, states, environmentalists, and academics.

In soliciting an EPA article for one of our stakeholder comment issues of EM, we usually work through the air or waste EPA program offices. In this search, as the head of the policy office, you were recommended as the best contact for this request. Some specifics. We are looking for an article of 2000 to 3000 words in length that focuses on EPA's priorities, particularly for air and waste management. You are free to go beyond those areas, and it could be authored by you or anyone you believe would be an appropriate to represent EPA's perspectives. We are asking authors to provide a near final draft by the end of June, but can be somewhat flexible as the normal review process does not apply for policy related opinion pieces. You would have a chance to review the galley proofs of the article before it goes to publication.

I hope you will consider our request as an opportunity to communicate directly with our members. If you have any questions in making a decision, please let me know. I'm available either through this email or by phone at 919 619-0769.

Thank you for your consideration.

John Bachmann  
Vision Air Consulting, LLC  
EM Editorial Board

**To:** Jackson, Ryan[jackson.ryan@epa.gov]; Lyons, Troy[lyons.troy@epa.gov]  
**From:** Greaves, Holly  
**Sent:** Mon 7/24/2017 7:09:31 PM  
**Subject:** RE:  
HAC QFRs Hill 07.21.17 FINAL.DOCX

Yes, please see attached.

I took a quick review, and the 4 questions/answers that reference ozone are below.

Jenkins Q1 & Q2  
McCollum Q170 & Q174

If OIRA can tell us today what edits they would like, we can work through the staff on appropriations to make the change, assuming they are minor edits. Right now we do not anticipate this resulting in a notation of late response on the record, but sooner rather than later is better.

We will make sure to review the senate transcript for inserts needed.

---

**From:** Jackson, Ryan  
**Sent:** Monday, July 24, 2017 2:49 PM  
**To:** Greaves, Holly <greaves.holly@epa.gov>; Lyons, Troy <lyons.troy@epa.gov>  
**Subject:**

Holly will you send me the QFRs for the House?

Is there an opportunity to ensure the ozone questions are accurate with resending the whole set of answers with the additional McCollum questions?

We really have to be attentive in the hearings to answer what the members ask live in addition to in QFRs. For example, in the Senate hearing there were requests that Daines made live which may not be encompassed in his QFRs.

Thank you.

Ryan Jackson  
Chief of Staff  
U.S. Environmental Protection Agency  
(202) 564-6999

**To:** Bolen, Brittany[bolen.brittany@epa.gov]  
**Cc:** Flynn, Mike[Flynn.Mike@epa.gov]; Richardson, RobinH[Richardson.RobinH@epa.gov]; Grantham, Nancy[Grantham.Nancy@epa.gov]; Rees, Sarah[rees.sarah@epa.gov]; Kime, Robin[Kime.Robin@epa.gov]  
**From:** Torma, Tim  
**Sent:** Fri 8/4/2017 7:04:43 PM  
**Subject:** 08/04/2017 Hot Topics  
Hot Topics 08-04-2017.docx

Brittany,

Attached are the hot topic items pulled from the weekly reports as well as updates to the list of pending items. Please let me know if you or others want more information on any of the items or have any questions. Have a good weekend!

TT

**To:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Thur 7/20/2017 1:15:33 PM  
**Subject:** OP comments on ozone report  
RptToCong Coop Agree 7 13 17 w BE and AL edits -- Draft.docx  
ATT00001.txt

**To:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]  
**Cc:** Samantha Dravis (dravis.samantha@epa.gov)[dravis.samantha@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Mon 7/24/2017 11:34:56 PM  
**Subject:** OAR air trends report  
[Hot Topics 07-21-2017.docx](#)

Hey, I was just going over the hot topics list and noticed OAR is planning to post its updated air trends report this week. Just want to make sure you're aware and coordinating with OPA. Here was the blurb from the weekly report:

|                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>OAR: Air Quality Trends through 2016</b> | <b>Next week OAR plans to post on-line an update to the trends report to reflect air quality monitoring data through 2016. Key messages this year include:</b> <ul style="list-style-type: none"><li>• Driven by state and federal work to cut pollution from stationary and mobile sources, emissions of key air pollutants continue to decline from 1990 levels.</li><li>• Between 1970 and 2016, the combined emissions of the six common pollutants, including particulate matter and sulfur dioxide, dropped by 73 percent. This progress occurred while the U.S. economy continued to grow, Americans drove more miles and population and energy use increased.</li><li>• Through successful state led implementation, numerous areas across the country are showing improvement in meeting national ambient air quality standards (NAAQS), and fewer areas are in nonattainment.</li></ul> |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

---

**From:** Torma, Tim  
**Sent:** Friday, July 21, 2017 4:25 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Cc:** Flynn, Mike <Flynn.Mike@epa.gov>; Rees, Sarah <rees.sarah@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>  
**Subject:** 07/21/2017 Hot Topics

Brittany,

Attached are the hot topic items pulled from the weekly reports. Please let me know if you or others want more information on any of the items or have any questions. Have a good weekend!

TT

**To:** Weekly Report Group[Weekly\_Report\_Group@epa.gov]  
**Cc:** Minoli, Kevin[Minoli.Kevin@epa.gov]; Packard, Elise[Packard.Elise@epa.gov]; Schwab, Justin[schwab.justin@epa.gov]; Fotouhi, David[fotouhi.david@epa.gov]; Greenwalt, Sarah[greenwalt.sarah@epa.gov]; Brown, Byron[brown.byron@epa.gov]; Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]; Dravis, Samantha[dravis.samantha@epa.gov]; Jackson, Ryan[jackson.ryan@epa.gov]  
**From:** Baptist, Erik  
**Sent:** Thur 7/20/2017 11:23:49 PM  
**Subject:** RE: OGC's Weekly Report  
[OGC Weekly Report 7.20.17.docx](#)

Attached please find a *phone-friendly version* of the OGC Weekly Report. Please feel free to reach out with questions.

Best,

**Erik Baptist**  
Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)

---

**From:** Baptist, Erik  
**Sent:** Thursday, July 20, 2017 7:17 PM  
**To:** Weekly Report Group <Weekly\_Report\_Group@epa.gov>  
**Cc:** Minoli, Kevin <Minoli.Kevin@epa.gov>; Packard, Elise <Packard.Elise@epa.gov>; Schwab, Justin <schwab.justin@epa.gov>; Fotouhi, David <fotouhi.david@epa.gov>; Baptist, Erik <baptist.erik@epa.gov>; Greenwalt, Sarah <greenwalt.sarah@epa.gov>; Brown, Byron <brown.byron@epa.gov>; Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Dravis, Samantha <dravis.samantha@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
**Subject:** OGC's Weekly Report

Attached please find OGC’s Weekly Report. Please feel free to reach out with questions.

Best,

**Erik Baptist**  
Senior Deputy General Counsel  
Office of General Counsel  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
(202) 564-1689  
[baptist.erik@epa.gov](mailto:baptist.erik@epa.gov)



**To:** Brown, Byron[brown.byron@epa.gov]  
**From:** Paul Balserak  
**Sent:** Wed 7/19/2017 9:38:14 PM  
**Subject:** CERCLA 108b Hardrock Mining Comments on Iron Ore Mining  
[MDEQ OGMD Resp USEPA HardRock Mining Rules 2017.pdf](#)  
[IMA - CERCLA 108b Final 7 11 17.pdf](#)  
[Proposed FR Rule for the Hardrock Mining Industry.pdf](#)  
[CERCLA 108b Hardrock Mining One Pager for EPA Meeting final.pdf](#)  
[AISI -- Comments on EPA Financial Responsibility Requirements under CERCLA 108b for Hardrock Mining.pdf](#)  
[CERCLA 108\(b\) Proposal -- Industry Coalition Comments.pdf](#)

Dear Byron,

Thank you again for meeting with my members and me on June 20th regarding the CERCLA 108b hardrock mining proposed rule. Attached for your convenience are comments/materials specific to the iron ore mining issue which were submitted to EPA by the July 11, 2017 comment period due date. Included are the following:

- AISI Comments on the CERCLA 108b Hardrock Mining Proposed Rule
- AISI CERCLA 108b Hardrock Mining One Pager for June 20 2017 EPA Meeting
- Michigan DEQ Comments on CERCLA 108b Hardrock Mining Proposed Rule
- Minnesota DNR Comments on CERCLA 108b Hardrock Mining Proposed Rule
- Iron Mining Association Comments on CERCLA 108b Hardrock Mining Proposed Rule

I have also attached comments prepared by a coalition of industry groups, including AISI, which address more generally the CERCLA 108b Hardrock Mining proposed rule requirements.

We continue to believe that the CERCLA 108b hardrock mining requirements as laid out in the Dec 2016 proposal would be impossible for our industry to comply with if finalized as is. We also continue to believe that iron ore mining should have never been included among the high risk mining categories that will ultimately be subject to the final rule requirements. If we can answer any questions or aid in any way, please do not hesitate to let me know. Hope you are doing well.

Best regards,

Paul

**Paul Balserak**  
Vice President, Environment

American Iron and Steel Institute  
25 Massachusetts Ave. NW, Suite 800  
Washington, DC 20001  
202 452-7122 (office)  

Personal Phone / Ex. 6

 (mobile)

**To:** Gunasekara, Mandy[Gunasekara.Mandy@epa.gov]  
**Cc:** Dravis, Samantha[dravis.samantha@epa.gov]  
**From:** Bolen, Brittany  
**Sent:** Mon 7/24/2017 11:34:56 PM  
**Subject:** OAR air trends report  
[Hot Topics 07-21-2017.docx](#)

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|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
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|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

---

**From:** Torma, Tim  
**Sent:** Friday, July 21, 2017 4:25 PM  
**To:** Bolen, Brittany <bolen.brittany@epa.gov>  
**Cc:** Flynn, Mike <Flynn.Mike@epa.gov>; Rees, Sarah <rees.sarah@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Richardson, RobinH <Richardson.RobinH@epa.gov>  
**Subject:** 07/21/2017 Hot Topics

Brittany,

Attached are the hot topic items pulled from the weekly reports. Please let me know if you or others want more information on any of the items or have any questions. Have a good weekend!

TT

**To:** Kenny, Shannon[Kenny.Shannon@epa.gov]  
**From:** Torma, Tim  
**Sent:** Mon 6/5/2017 1:23:48 PM  
**Subject:** RE: Inside EPA: White House Seen Backing Push To Overhaul 'In-The-Weeds' EPA Policies

Here is the text:

## **White House Seen Backing Push To Overhaul 'In-The-Weeds' EPA Policies**

June 02, 2017

The White House appears to be supporting states' calls to overhaul smaller "in-the-weeds" EPA rules such as ending a policy permanently subjecting units to air toxics limits and easing paperwork mandates, seeing backing for targeting these less-prominent rules in lieu of calls to undo "big ticket" Obama-era policies, an industry source says.

While much attention on comments in response to President Donald Trump's deregulatory executive orders (EO) has focused on challenges to landmark rules such as the Clean Power Plan greenhouse gas standards for power plants and Clean Water Act jurisdiction rule, the source suggests lesser-known rules could be more viable targets for the regulatory reform push -- particularly a slew of administrative and other regulations that states have identified.

The industry source says that stakeholders who heard from administration officials were surprised they were interested in hearing state and local concerns beyond "some of the high profile/big ticket items" and "wanted to hear from co-regulators on more technical, in-the-weeds examples of burdensome regulations."

EPA Administrator Scott Pruitt established a regulatory reform task force to assess potential regulations that could be subject to Trump's EO 13777, which calls for agencies to establish regulatory reform task forces to review existing rules to "repeal, replace or modify"; and EO 13771, better known as the "two-for-one" order that requires agencies to repeal two existing rules for every one new rule and meet a \$0 net regulatory cost target.

The agency's air, water, toxics and other divisions held a series of meetings to seek input on rules that could be subject to the regulatory reform effort, and also took written comment through May 15.

In comments, groups such as the Environmental Council of States (ECOS) -- representing many state environmental agencies -- identified rules and policies across the spectrum of EPA authority for overhaul and, in most cases, eliminating entirely, due to overlapping state requirements.

ECOS and others, in their comments, addressed a wide range of major rules and less-prominent policies, including the Clean Water Act (CWA)'s sewage overflow requirements, National Pollution Discharge Elimination System permits and the CWA jurisdiction rule, to the Clean Air Act's "Once in, Always in" air toxics policy and its maintenance area monitoring requirements, to a host of Superfund rules and regulations.

The industry source says Pruitt and his task force "were very interested in hearing from state, local, and tribal agencies on their priorities for regulatory reform," and said some of the interest was likely due to Pruitt's "interest in animating cooperative federalism," which he has called a priority during his tenure.

Cooperative federalism in this context refers to the balance between EPA and state authority over environmental regulation, and Pruitt has said he wants to return more of that power to states.

### **'In-The-Weeds' Rules**

The administration might now look to the "in-the-weeds" rules identified by states as a priority under the reform push, the industry source says. "We have heard directly from the Regulatory Reform Task Force and the White House on their interest in hearing/addressing some of the key regulations identified by state, local, and tribal governments, so we are hopeful that some of the

weedier suggestions may be considered,” the source says.

The source says states and industry groups concur with the administration that addressing environmental rules through EO 13777 is a “key opportunity to weigh in at the intersection of several interagency processes,” particularly after the Department of Commerce received what the source called “relatively limited responses” to its request for comments on the impact of federal permitting requirements on domestic manufacturing.

The “technical regulatory actions” that the source says states identified and would likely be “welcome suggestions” to the administrative officials -- and more easily addressed under the EO -- include the Clean Air Act's “Once In, Always In” policy as well as general “paperwork, reporting or permitting requirements.”

The “Once In, Always In” policy currently requires sources subject to maximum achievable control technology (MACT) thresholds to always be subject to the same MACT standard, regardless of whether they reduce their emissions of hazardous air pollutants (HAPs). States say this policy fails to encourage additional air toxics reductions if facilities know they can never avoid MACT regulation even if they cut their emissions.

The Northeast States for Coordinated Air Use Management, for example, [said in comments](#) that reconsidering this policy would “reduce administrative and reporting burdens,” but says it must be “contingent upon the pollution prevention measures being permanent and enforceable through permit conditions.”

The Association of Air Pollution Control Agencies [echoed this request](#), arguing that the current policy “can unfairly limit the abilities of subject sources to make modifications or operate in a competitive market.”

As part of the regulatory reform push, the industry source says the administration also welcomes technical suggestions that target repeal of “paperwork, reporting and permitting” requirements. ECOS in its comments mentioned requirements, such as the Superfund program's cooperative Agreements for Superfund Response Actions in state contracts, arguing in part that state staffs already do much of the work on these grants and agreements, and detailed reports are “burdensome.”

The Western Governors' Association, in addition to recommendations to “clarify key enabling statutes” -- CWA, the Clean Air Act, the Resource Conservation and Recovery Act (RCRA) and Superfund -- [asked in its comments](#) that EPA “recognize states' exclusive authority” over a variety of permitting programs, such as state water quality standards and setting Total Maximum Daily Loads (TMDLs), avoiding duplication of state programs, and publish “timely guidance” for states, particularly in implementing the stricter 2015 ozone ambient air standard.

### **States' Suggestions**

Other state environmental agencies, such as South Carolina and Ohio, asked EPA to reexamine its Title V operating permit program for emissions. The Ohio EPA, [in its comments](#), pointed out that EPA has yet to respond to a 2006 task force report in which stakeholders gave input on the program and identified “much-needed improvement” to the permit system. Both states also asked EPA to examine how it expects states to “demonstrate compliance” with its Cross-State Air Pollution Rule (CSAPR) emissions trading program standards for nitrogen oxides.

“It is an unreasonable burden and complete waste of resources to continue to demonstrate compliance with requirements that no longer have a real impact on air quality, as they have been effectively superseded by more stringent rules,” the Ohio EPA writes in its May 15 comments. --

*Amanda Palleschi* ([apalleschi@iwpnews.com](mailto:apalleschi@iwpnews.com))

Related News | [Transition 2016-2017](#) | [Air](#) |

202399

**From:** Kenny, Shannon

**Sent:** Monday, June 05, 2017 9:22 AM

**To:** Torma, Tim

**Subject:** Re: Inside EPA: White House Seen Backing Push To Overhaul 'In-The-Weeds' EPA Policies

Hi, will you send me article text? Can't figure out log in, and am at home today.

Also, will you cover senior staff and report back anything interesting? No administrator or Ryan today, but they could have it anyway. Brittany would go, too.

Sent from my iPad

On Jun 5, 2017, at 8:53 AM, Torma, Tim <[Torma.Tim@epa.gov](mailto:Torma.Tim@epa.gov)> wrote:

<https://insideepa.com/daily-news/white-house-seen-backing-push-overhaul-weeds-epa-policies>

Tim Torma

Senior Advisor

U.S. EPA Office of Policy

202-566-2864

**To:** McCluney, Lance[McCluney.Lance@epa.gov]; Kenny, Shannon[Kenny.Shannon@epa.gov]; Campbell, Jennie[Campbell.Jennie@epa.gov]  
**Cc:** Benton, Michael[benton.michael@epa.gov]  
**From:** Kime, Robin  
**Sent:** Fri 6/30/2017 4:41:03 PM  
**Subject:** RE: Status of QFRs  
OP Budget QFRs Final.docx

Good afternoon,  
The attached response was sent to Holly at noon today.

-----Original Message-----

From: McCluney, Lance  
Sent: Friday, June 30, 2017 12:37 PM  
To: Kenny, Shannon <Kenny.Shannon@epa.gov>; Campbell, Jennie <Campbell.Jennie@epa.gov>; Kime, Robin <Kime.Robin@epa.gov>  
Cc: Benton, Michael <benton.michael@epa.gov>  
Subject: Status of QFRs

Hello All,

I am just checking in on the status of the QFRs assigned to OP. They were due to OCFO at noon today.

Thanks,  
Lance

Sent from my iPhone